EPA Registration No. 39967-137 Vol. 1

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ANTEC INTERNATIONAL LTD. C/O DR ALAN WAGNER, DVM, MS 2821 RIVER PARK DR COLUMBUS, OH 43220

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/09/96. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Studies 01 - 04 were all rejected for the following reasons/s:

* You failed to sign the statement of data confidentiality claims included in the study.

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Studies 03 - 04 were all rejected for the following reasons/s:

* Your Statement of No Data Confidentiality Claims is contradicted by the marking(s) on page(s)

3 of the study. If you do not intend to make Supplemental

Claims of Data Confidentiality you can explicitly override these markings when you resubmit this study.

DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2821 River Park Drive-Columbus, Ohio 43220 Ph: 614/459-5965 Fax: 614/459-9875

October 8, 1996

Document Processing Desk (Amendment)
Mr. Walter C. Francis
Acting Product Manager (PM 32)
Antimicrobial Program Branch
Registration Division (H7505C)
Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Submittance of Amendment for Updating and Revision of Labeling for our formulation, Virkon-S EPA Registration No. 62432-1

Dear Mr. Francis:

Please find attached an Application Amendment for Updating and Revision of Labeling for Our Formulation, Virkon-S (EPA Number 62432-1).

This amendment follows the approval by the agency of our revised labeling of June 26, 1996 in accordance with the letter of March 7, 1996 from Mrs. Ruth Douglas.

The attached application for updating and revising our Virkon S labeling concerns an expansion of our efficacy claims based upon the recent completion of studies by laboratories in accordance with AOAC and GLP standards.

Also, please find enclosed as an attachment, supportive data for VIRKON-S claims for animal application and egg sanitizing as described in the proposed labeling.

The supportive data for the claims identified in the labeling is listed in the attachment as follows:

- (1) Investigation to Test the Effect of Prolonged Spraying of Livestock With Virkon-S Rejected Study (c)
- (2) Trials in Poultry With a Sprayed Disinfectant Virkon-S Rejected Study (62)
- (3) Eye Irritation Study in the Rabbit Virkon-S (1.0% W/V) Rejected Study (183)
- (4) Skin Irritation and Corrosivity Study in the Rabbit Virkon-S (1.0% W/V) Rejected Study (64)

Mr. Walter C. Francis Acting Product Manager (32) Page 2

We appreciate your advice and assistance in the preparation and submissions of previous applications to your division, Mr. Francis, and will be looking forward to your review, comments and approval of this application.

Respectfully submitted,

De, alara. Wzyna

Dr. Alan R. Wagner, D.V.M., M.Sc. Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL - 3 copies

cc: Mr. Francis Auchincloss Antec International Ltd.

Reviewer ID DEMESME Submission No. 55-12980 Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 62432-1 PM 32 Action Code 300 10 Descriptor (Amend/Resubmisions only) Final/ / 601 |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / (C) Certification Packaging / /(S) Service Person 20 Registration Type: / (R) Non-residential Use Only (1) Conditional (2) Unconditional / (N) Not-Applicable 25 Proposed Classification: 30 Final Classification: // (R) Restricted // (R) Restricted (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: 40 Date Received by PM 10 17 01/916 017 019 916 1017 11/916 MD DAY YR MD DAY YR MD DAY YR |80| Method of Support: // (1) Cite-All // (6) Owner Submission. // (4) Not Applicable // (7) Total Submission / / (5) Not Submitted / / (8) Selective Method DATE DUE DATE RESPONSE RESPONSE SENT Reviewers Requested: DATE RETURNED CODE DATE CH EF PL DEB NDEB TB EEB **EFGB** 115 FINAL Response ACTION Code 37 120 Response 017 1196 and Pet 82-2 75-DAY RESPONSE DUE DATE: / /(Y) Yes / /(N) No

DR. ALAN R. WAGNER

Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2821 River Park Drive Columbus, Ohio 43220 Ph: 614/459-5965 Fax: 614/459-9875

July 1, 1996

Document Processing Desk (Amendment)
Mr. Walter C. Francis
Acting Product Manager (PM 32)
Antimicrobial Program Branch
Registration Division (H7505C)
Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Attn: Mr. Robert Travaglini

Re: Virkon S

EPA Registration No. 62432-1 Resubmssion of May 22, 1996 and Submission of Finished Labeling

Dear Mr. Travaglini:

In accordance with our telephone conversation and your letter of June 26, 1996 regarding this subject, please find enclosed as requested, one copy of the finished labeling before releasing the product for shipment.

final labil

Thank you for your concern regarding the location of the application and your excellent assistance of expediting the sending of the approved labeling.

I hope to have the opportunity to meet with you during my next visit to Washington, D.C. and please give my best regards to Mr. Francis.

Sincerely,

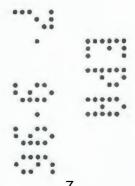
Alan R. Wagner, D.V.M., M.S.

Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

ec: Francis Auchincloss
Antec International Ltd.



BROAD SPECTHUM DISINFECTANT

VPRICNI S is effective against numerous microorganisms affecting swhmist, viruses, Gens positive and Gens negative bacteries, fund (nodes and yeasts), and Mycopismus. Efficacy was determined in the presence of hard water and organic maternal.

GREGOTION FOR USE.

Federal the pothbits were of their product in a manner inconsistent with its labelling. This powder formule is easily dished for use in manual or mechine operations.

POLICITY PRODUCTRON/RATITE PRODUCTION

WINKON S is recommended for use in hallberine, in chicken houses in Reitite production and execution determinant of the use in hallberine, in chicken houses in Reitite production.

and processing plants.

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according to manufacturer's use detectors.

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PROCESSING PLANTS: For deinfecting and cleaning wells, cultings and floors, spray at a

situion of 1% (1:100). STURMADE & DISPOSAL. Store in a cool, dry plece in lightly doued consimer. Naep out of mosts of children. Alemps replace fol after use. Wash emply container forcoughly and dispose of in issue).





VILKOL®

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

polococcus pyogenes. Campylobacter pylordis. Kebseells pneumoniae herchis cdi. Salmonells typhimurium. Salmonells doleraesuis, sudomonas seruginosa. Staphylococcus aureus. Staphylococcus epide oplissma galiseapticum. Clostridium perfringens. Bordeslella avium

Newcastle Disease, Infactious Brenchitis, Infactious Bursal disease, Avian Laryngobachelle, Avain Influenca, Marak's Disease, Egg Drop Syndro Duck Viral Entertis, Turkey Herpes Virus, Anican Swine Fever.

Aspengillus flavus, Aspengillus fumigatus, Candida albicans

ICTIVE INGREDIENTS

INERT INGREDIENTS

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

Distributed by and manufa

Olbs Net Weight



Durvet Inc. Blue Springs, Missouri, 84014-1-900-821-9570 Made in England by Antec International Limited VIRKON S e a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512









BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

pisooocus pyogenes, Staphylooocus surus, Klabaielle praumonise, Escheriche Salmonella lybinnutiem, Salmonella cholemesus, Previdentonas sanginosa, hyloococus spidermidis. Mycopisams gallespisoum, Bordetalla bronchlespisoa, surelle mulicolde, Campylobadar pyloride, Costidum perfingens, cobacilius poleuropnaumoniae, Traponeme hydolysantsinies, Bordetalla seriem.

log cholere, Swine influence, Poncine parvovinus, Rotavirei diembee, Nascular etemetitis, Pseudorabies, PRBS (Porcine Raproductive & Respiratory lyndroms), African Swine Feres.

Aspergillus Nerves, Aspergillus fumigates, Candida albicana, Fusarium montifico

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed by and manufactured for



Durvet Inc. Blue Springs, Mesouri, 64014-1-800-821-5670 Made in England by Antac International Limited VIBXON S is a registered trademant of and manufactured by Arriac International Limited
U.S. Patent No. 4822512



In Accordance with PR Wolles 82-S. Sensed on Draft Labeling Daied

DILUTION CHART

1% Solution 2% Solution	1.3 cunces 2.7 cences 13.4 cunces 26.7 cunces 66.8 cunces	
Final Solution	American 1 gallon 10 gallons 50 gallons	



For DISHNEECTING use a rate of 7.5 gallone/1000 sq. ft. For CLEARING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft. The manuary cap habbs with Made with Made town 17.5 earnoss.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Powder is corrosivo. Causes sidn burns and ineventible eye demaga. Harmfal il swellowed, abecided through alike, or Inhabed. Do not got in eyes, on sidn, or or clothing. Wear protective dioding, and nutbor gloves. Avoid treathing dust. Wear goggles, isoe abletid, or safety glasses. Weah harst birnovarity with soop and walter ablet safety. Remove contaminated clothing and weath before walter dust handling, statement refers to powder only, not in use solution.

PRACTICAL TREATMENT

F. N. EYEB: Hold eyelids open and flush with a sheady, gentle stream of water for 15 minutes. Get prompt medical attention. F. ON SKIN; Wash with plenty of soop and water. Get medical intention if installon persists.

F SWALLOWED: Drink promptly a large quentity of water. Avoid sizobol. Get immediate medical attention. IF INMALED or symptoms of coupling, choking, or wheezing are iroublescene, remove to fresh air and seek medical attention. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gestric lavage.

durvet

Manufactured for Durvet Inc. Blue Springs, Missourt, 64014-1-800-821-5570

EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001 Made in England by Antec International Limited

Reviewer ID TRANAGLINI Submission No. S 507679 Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENUMENTS File Symbol/Reg. No. 102432-1 PM 32 Action Code 30/ 10 Descriptor (Amend/Resubmisions only) ______ Associal Cabelians |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / /(C) Certification Packaging / (N) No /(S) Service Person |20| Registration Type: / (R) Non-residential Use Only (1) Conditional / (2) Unconditional / (N) Not-Applicable |25 | Proposed Classification: |30 | Final Classification: / / (R) Restricted / / (R) Restricted (G) General (N) Not Classified |35| Date on Application: |04| EPA Received Date: |40| Date Received by PM 16 245 816 16 24 816 MD DAY YR MO DAY YR [80] Method of Support: // (1) Cite-All // (6) Owner Submission (4) Not Applicable (7) Total Submission / (5) Not Submitted // (8) Selective Method DATE DUE DATE RESPONSE RESPONSE Reviewers Requested: SENT DATE RETURNED CODE DATE CH EF PL DEB NDEB TB EEB **EFGB** 115 FINAL Response 120 Response ACTION Code 75-DAY RESPONSE DUE DATE: / /(Y) Yes / /(N) No

JUN 2 6 1996

Antec International Limited Chilton Industrial Estate Sudbury, Suffolk C010 6XD England

Attn: Dr. Alan Wagner, D.V.M., M.S.

Authorized U.S. Agent for Antec International Ltd.

Subject: Virkon S

EPA Registration No. 62432-1 Your Resubmission of May 22, 1996

The submitted product labeling, revised in accordance with EPA's letter of March 7, 1996 has been reviewed and the following comments apply.

- The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Submit one copy of the finished labeling before releasing the product for shipment.
- You are reminded that although supportive data for nonhuman related claims do not have to be submitted to the Agency, you are required to have satisfactory data in your files for these claims and to be able to provide it to the Agency upon request.

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,

R.J. for

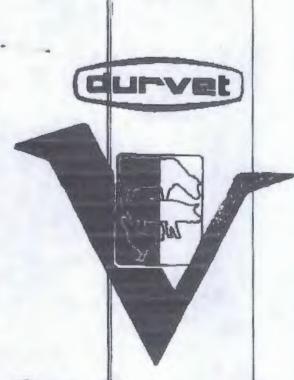
Walter C. Francis Acting Product Manager (32)

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Printed on Recycled Paper

*U.S. Government Printing Office: 1992 — 620-856/40672



Virkon. S

BROAD SPECTRUM DISINFECTANT

For Use in Clearing and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

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FLINDS

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KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Pahel for Additional Precautions

10hs Net Weight

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resp. Minmurt, 5631 A-1-800-631-5570 Made in Engineed by Artic Interruptional United

VIPODAY S is a regulated trademark of and manufactured by Artist International Laboratory

ACCEPTED

JUN 26 1996

cade Act, as amended, for the 10000 POR D No Me 102432-1

irkon.S

SILUTION CHART

Describly of Final Solution	1% Salution	2% Substian		
Americae 1 gallon 10 gallons 50 gallons	1.3 demons 13.4 guestis 66.6 dueses	2.7 punces 26.7 punces 133.5 punces		





DISHERECTRIC uno a cons of 7.5 gallors/1000 as it. CLEANING AND OURSECTION und prop of 15 gallors/1000 as it.

RECAUTIONARY STATEMENTS

AZARDS TO HUMANS AND DIRESTIC ANIMALS

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ACTICAL TREATMENT

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er ins. Blue Springs, Missouri, 64214-1-800-821-5570

Made in England by Anley International Limited EFF Flog. No. 62432-1-12281. EPA Est. No. 65432-EN-001

EQUINE BACTERIA Clostridial diarrhea Fistulous Withers (Poll Evil) Taylorella equigenitalis Streptococcus equi (Strangles)

Pseudomonas mallei (Glanders)

Bordetella bronchiseptica **EQUINE VIRUSES**

African Horse Sickness

African Viral Arteritis (Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis Equine Infectious Anemia (Swamp Fever)

Equine papillomatosis

Equine Contagious Abortion Adenovirus Pneumonia

Equine Influenza (The Cough)

EQUINE FUNGI

Dermatophytosis (Ringworm) Dermatophylosis (Mud Fever)

Fuszerum moniliforme

VE BACTERIA Moraxella bovis

Mycobacterium bovis Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Bovine Adenovirus Type 4 **Pseudorabies**

Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

Antec International

V (Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

VIRUSES

BACTERIA

Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus epidermidis Duck Herpes Virus Mycoplasma gallisepticum Clostridium perfringens

Bordetella avium

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Candida albicans Avian Laryngotracheitis Avian Influenza Marek's Disease

Egg Drop Syndrome Turkey Herpes Virus **Duck Viral Enteritis**

FUNGI

Aspergillus flavus Aspergillus fumigatus

SWINE BACTERIA Bordetella bronchiseptica Pasteurella multocida Actinobacillus pleuropneumoniae Treponema hyodysenteriae. Clostridium perfringens **SWINE VIRUSES** Hog Cholera Swine Influenza Porcine parvovirus Rotaviral diarrhea Vesicular stomatitis **Pseudorabies** Porcine Reproductive and Respiratory Syndrome (PRRS) African Swine Fever Foot and Mouth Disease SWINE FUNGI Fusarium moniliforme COMPANION ANIMALS BACTERIA Streptococcus aureus Streptococcus pyogenes Klebsiella pneumoniae Pseudomonas aeruginosa VIRUSES Canine Parvovirus Distemper Leptospira canicola Feline parvovirus Feline herpes Feline calicivirus FUNGI

ACTIVE INGREDIENTS Polassium peroxymonosuliato...... 20.4% Sodium Chloride..... INERT INGREDIENTS...... 78.1% TOTAL

Equivalent to 9.75% Available Chierine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England . Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846 ACCEPTED JUN 26 1996

Microsporum canis

VIRKON S is a registered trademark of and manufactured by Antec international Limited

U.S. Palent No. 4822312

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis.

Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium and Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Porcine Parvovirus, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, African Swine Fever and Foot and Mouth Disease. Bacteria of Pleuropneumonia, Treponema hyodysenteriae, and Clostridium perfringens. Fungi: Fusarium moniliforme.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH
FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

For Topical Use On Animal: Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day Repeat as necessary. Stables, Horse Boxes, Tack Equipment and Feed-Rooms; Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases; By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi; Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), and Fusarium moniliforme.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Moraxella bovis, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

Virkon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. Virkon S at 1% solution is generally suitable for cleansing and disinfection

COMPANION ANIMALS

CONTROLS: Viruses Canine Parvovirus, Distemper, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.

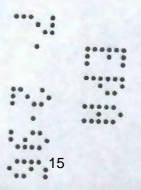
COMPANION ANIMALS

APPLICATIONS:

Virkon S is recommended as a "one step" cleaning and disinfection procedure for all surfaces, equipment, instruments, utensils and caging systems associated with Veterinary Medical Hospitals, infectious disease wards, quarantine areas, Humane Society facilities, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles.

DIRECTIONS FOR USE:

Add the contents of one Virkon S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not immerse metal objects in Virkon S for long periods - 10 minutes is maximum contact time.



BACK PANEL DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125 g	6 oz	
100 g	5 oz	The measure cap holds when filled
75 g	4 oz	level 500 g or 17.5 ounces.
50 g	3 oz	
	2 oz	Brim full - contains 200 g or 17 ounces.
	1 oz	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

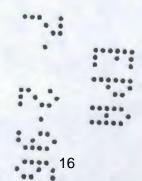
IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose in trash. Do not mix this product with other chemicals.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk C010 6XD, England
Tel: (1787 77305 Telx: 987495 Fax: (1787) 310846



FIVE (5) COPIES OF REVISED LABELING

DR. ALAN R. WAGNER

Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2821 River Park Drive Columbus, Ohio 43220 Ph: 614/459-5965 Fax: 614/459-9875

June 25, 1996

Document Processing Desk (AMENDMENT) Mr. Robert Travaglini, PM 32 (H7505C) Office of Pesticide Programs 401 M Street SW Washington, DC 20460 Original Copy

Re: Resubmittance of Revised VIRKON S (EPA No., 62432-1) Master Labeling in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

Dear Mr. Travaglini:

The enclosed three copies of the above described submission is being resubmitted to replace the copies that were hand delivered to the Document Desk on May 22, 1996 and stamped.

In accordance with your telephone request on June 25, 1996 these replace the copies that have not been located by your department.

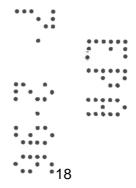
If any further information is necessary, please contact me by phone or fax at the numbers indicated above.

Sincerely,

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL



Reviewer ID TRANAGLINI Submission No. S 506/12 Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENUMENTS File Symbol/Reg. No. 10 2432-1 PM 32 Action Code 201 | 10 | Descriptor (Amend/Resubmisions only) |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / (C) Certification Packaging / (N) No /(S) Service Person |20| Registration Type: (R) Non-residential Use Only // (1) Conditional // (2) Unconditional / (N) Not-Applicable |25 | Proposed Classification: |30 | Final Classification: // (R) Restricted /7 (R) Restricted / / (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: |40 | Date Received by PM 15 3 2 9 6 MO DAY YR [80] Method of Support: / (1) Cite-All [[6] Owner Submission / / (4) Not Applicable / (7) Total Submission / / (5) Not Submitted / / (8) Selective Method DATE DUE DATE RESPONSE RESPONSE Reviewers Requested: SENT RETURNED DATE CH EF PL DEB NDEB TB EEB EFGB |120 | Response 115 FINAL Response 75-DAY RESPONSE DUE DATE: //(Y) Yes //(N) No

20

Private Consultant Clinical Investigations

River Park Drive mbus, Ohio 43220 96 MAY 22 P3 24

Ph: 614/459-5965 Fax: 614/459-9875

May 22, 1996

Mr. Walter C. Francis
Acting Chief
Antimicrobial Branch (APB)
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA. 22202

Re: Resubmittance of Revised VIRKON S (EPA No. 62432-1) Master Labeling in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

Dear Mr. Francis:

Pursuant to our meeting of May 2, 1996 and discussion/review of our VIRKON S labeling, please find attached the label revisions prepared in accordance with the letter of March 7th from Ms. Douglas and as you advised, for your review.

I do want to thank you for the opportunity to meet with you on May 2, 1996 and your excellent assistance and advise and the courtesy extended to me. Also, I appreciated being informed of the memorial service planned for Ms. Douglas and I will be in attendance.

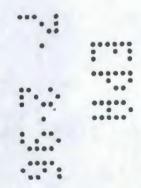
I hope the resubmittance of the revised labeling will be acceptable and approved.

Sincerely,

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd.

ARW/mw

VIA PERSONAL DELIVERY



(A) SEP	United State Office App	tes Environmental P of Pesticide Program Washington, DC 2 plication for	ns (H7505C) (0460		Registrat Amendm .Other	ion	1910	mber
		Section	n I					
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62432-1				Walter C	. Franci		Name Con	stricted
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VIRKON S			Act	ing Chie:	E			
5. Name and Address of Ap	oplicant (Include ZIP (Code) .					FIFRA Section :	4 . 6 4 . 6
Antec Intgern Chilton Indus Sudbury, Suffo ENGLAND Check it this	strial Esta	te	to:	eg. No		ai in co	mposition and la	Ibeling
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7.		Jection		inal admind tab-t	t in topponent to			
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Resubmission in respo	inse to Agency letter	dated		Me Too* Applicat				
Notification - Explain be	alow		H.	MB 100 Applicat	on.			
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2. Five (5)	copies of	revised la	beling.					
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DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

RECD EPA/OPP/OPD1

Private Consultant Clinical Investigations

2821 River Park Drive Columbus, Ohio 43220 96 MAY 22 P3:24

Ph: 614/459-5965 Fax: 614/459-9875

May 22, 1996

Mr. Walter C. Francis
Acting Chief
Antimicrobial Branch (APB)
Registration Division (H7505C)
U.S. Environmental Protection Agency
Room 248, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA. 22202

Re: Resubmittance of Revised VIRKON S (EPA No. 62432-1) Master Labeling in Accordance With Letter of March 7, 1996 From Ms. Ruth Douglas

Dear Mr. Francis:

Pursuant to our meeting of May 2, 1996 and discussion/review of our VIRKON S labeling, please find attached the label revisions prepared in accordance with the letter of March 7th from Ms. Douglas and as you advised, for your review.

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I hope the resubmittance of the revised labeling will be acceptable and approved.

Sincerely,

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd.

ARW/mw

VIA PERSONAL DELIVERY

Washingto	e Programs (H7505C) on, DC 20460 on for Pesticid	ency	Registration Amendment Other	
	Section I			
Company/Product Number 62432 - 1		Product Manager Walter C		Proposed Classification
4. Company/Product (Name)	PM#			X None Restricted
VIRKON S	Act	ing Chief		
5. Name and Address of Applicant (Include ZIP Code)				rith FIFRA Section 3(c)(3)
Antec Intgernational Ltd. Chilton Industrial Estate Sudbury, Suffok C010 6XD ENGLAND Check if this is a new address	(b)(i), to:			composition and labeling
	Section I I			
		Final printed labels	in response in	
Amendment - Explain below		Agency letter dated		
Resubmission in response to Agency letter dated		'Me Too" Application	on,	
Notification - Explain below.		Other - explain belo	nat .	
Explanation: Use additional page(s) if necessary. (For se				
Material This Product Will Be Packaged in:	ection III		•	
Material This Product Will Be Packaged in: Child-Resistant Packaging Unit Packaging	Water Soluble	Packaging	2. Type of Contain	ner
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DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2821 River Park Drive Columbus, Ohio 43220 Ph: 614/459-5965 Fax: 614/459-9875

March 29, 1996

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (H7505C)
U.S. Environmental Protection Aency
Room 278, Crystal Mall II
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: VIRKON S

EPA Registration Number: 62432-1 Amendment Dated August 8, 1995 And Your Leltter of Response Dated March 7, 1996

Dear Ms. Douglas:

Thank you for your letter of March 7, 1996 in response to our amendment of revised master-labeling for VIRKON S. This label amendment superceded the ones dated April 11th and June 20th, 1995, as we agreed during our telephone conversation. I most certainly appreciated your assistance in this request.

I have reviewed and discussed with my client, Antec International, Ltd., your letter of March 7th, 1996 regarding your comments and unacceptability of the proposed labeling as submitted. Your letter proved most helpful in clarifying the issues in question as identified on the submitted labeling. We too had concerns that diseases rather than infectious organisms were present on previously approved labels.

Regarding our label claims for animal pathogens, these are zoonoses organisms, as you know, infecting both humans and animals and by default the reference refers to animal use only.

As a point of inquiry regarding the preparation of the resubmittance of an Application For Amendment in accordance with your letter of March 7, 1996, we would appreciate your review and guidance as to our proposals for acceptance and inclusion into our resubmitted Application For Amendment responding to the following points covered in your letter.

Comment # 1: "Delete Campylobacter coli and Campylobacter jejuni. These are also human pathogens.

Data required." ——— We have enclosed data as requested. See Ref. No. 23.

Comment # 2: "Delete Leptospirosis." ----- We will delete on resubmission.

Comment # 3: "Delete Salmonella enteritidis. This is a human pathogen. Data Required." ----- We have enclosed data as requested. See Ref. No's. 28 & 70.

Comment # 4: " Delete Parainfluenza. This is a human pathogen. Data required." ----- We have enclosed data as requested. ----- See Ref. No. 71.

Comment # 5: "Delete Leukoencephalomalacia and Moldy Corn Poisoning. These are diseases."

These disease entities will be deleted from label resubmission since the etiological agent is Fusarium moniliforme. We have enclosed data for this organism. See Ref. No. 73.

Comment # 6: "Delete Listeria monocytogenes. This is a human pathogen. Data required." ----- We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70.

Comment # 7: "Delete Erysipelothrix rhusiopathiae. This is a human pathogen. Data required."

We have enclosed data in reference to this organism being identified as a zoonotic disease. See Ref. No. 70

Comment # 8: "Delete Bovine viral diarrhea. This is a disease." ----This entity should be identified as BVD Pestivirus. We have enclosed data. See Ref. No. 71.

Comment # 9: "Delete Atrophic rhinitis, Colibacillosis, Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis. These are diseases." ------Atrophic rhinitis would be replaced by Bordatella bronchiseptica and Pasteurella multicida, both associated with this disease entity. We have enclosed data relating to this entity. See Ref. No's. 70 & 125.

Colibacillosis will be replaced with E. coli. Data is enclosed. See Ref. No. 109.

Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis will be deleted from the resubmitted label.

Comment # 10: "Delete Transmissible Gastroenteritis. This is a disease." ——— This entity will be replaced by TGE coronavirus. We have enclosed data. See Ref. No. 71.

Comment # 11: "Delete Parainfluenza, Infectious hepatitis and Oral papillomatosis. These are diseases." ------ We would modify this entity as Parainfluenza virus, being a zoonotic organism to which several livestock species are susceptible.

Infectious hepatitis would be deleted and replaced by Infectious canine hepatitis (Adenovirus). We have enclosed data. See Ref. No. 49.

Oral papillomatosis would be replaced by Bovine papilloma virus. We have enclosed data for this entity. See No's, 2 & 110.

Comment # 12: "Delete Coronavirus. This is both a human and animal pathogen. Data are required." ——
This pathogen will be replaced on the label by TGE coronavirus and Infectious bronchitis virus. We have enclosed data as requested. See Ref. No's. 71 & 131 respectively.

Comment #13: "Delete Rabies. This is a disease." ----- This entity will be deleted on resubmission.

Comment # 14 - 15: All references to use of VIRKON S in cleaning, sanitizing and disinfecting institutional and food processing and service facilities and references for use of product for the protection of hotel guests and ship passengers will be deleted in the preparation of the resubmittance of our Application For Amendment.

We are anxious to respond to your letter of March 7, 1996 and to amend our resubmission of VIRKON S Master Labeling in accordance with your comments and would appreciate your counsel and advice concerning our tentative responses to the comments defined in your letter.

Again, I want to thank you for the assistance and courtesy extended to me regarding our Regulatory Affairs concerns. I also hope, Ms. Douglas, that you have fully recovered from your illness and that I may have the opportunity to visit you in the near future. I would be most grateful for your advice and comments in reference to this submission.

Sincerely,

Alan R. Wagner, DVM., MS

Alan R. Wagner, DVM., MS
Agent for Antec International Ltd.

ARW/mw

VIA CERTIFIED MAIL

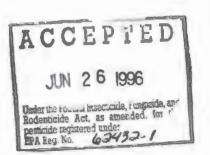
cc: Francis Auchincloss
Antec International, Ltd.

Reviewer ID Submission No. Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 62432-1 PM 32 Action Code 300 10 Descriptor (Amend/Resultations only) Amended 10 bels |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / /(C) Certification Packaging / / (N) No / /(S) Service Person 20 Registration Type: / (R) Non-residential Use Only (1) Conditional // (2) Unconditional / / (N) Not-Applicable |25| Proposed Classification: |30| Final Classification: // (R) Restricted // (R) Restricted (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: |40| Date Received by PM 018 110915 MD DAY YR 018/18/915 018 018 916 T |80 | Method of Support: (1) Cite-All // (6) Owner Submission. // (4) Not Applicable // (7) Total Submission / / (5) Not Submitted / / (8) Selective Method RESPONSE DATE RESPONSE DUE DATE SENT Reviewers Requested: RETURNED DATE CODE DATE CH EF PL DEB NDEB TB EEB **EFGB** 115 FINAL 120 Response Response ACTION Code /2 (N) No 75-DAY RESPONSE DUE DATE: / /(Y) Yes 28

mclark

New York





BROAD SPECTRUM DISINFECTANT

VIRICOLS is effective against numerous microorganisms affecting animals: wruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma Efficiery was determined in the presence of hard water and organic material. DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its liabelling. This powder formule is easily diluted for use in menual or machine operations POULTRY PRODUCTION/RATITE PRODUCTION

VIRIXON S is recommended for use in hatcheres, in chicken houses in Rathe production

and processing plants.

CONTROLS: Bacteria of Streptococcus pyegenes, Campyrobacter pytoridis, Klebarella pnewmeesse, Escherchia coli, Salmenella typhicisurium, Salmenella chotoraesses, Pseudemenaa atrugimosa, Staphyrococcus mureus, Staphyrococcus epiderimidis, Mycoplesma gatteapticum, Clossificium pertingens, Borderstita rrium. Virusea; Newcastle Deseas, Intectious Brenchits, Intectious Brunst disease, Avian Larympotrochetis, Aren Influenza, Marekti Disassa. Egg Drop Syndroma, Duck Viral Enteritis, Turtury Herpes Virus. African Swine Finer, Fung, Aporgillus Ravus, Aporgillus Ravus, Candida abicans.

HATCHERIES: VIRIOON S nt 1% colution is generaby suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humedinging systems, colling funs, chichen houses, transfer trucks. Iranys, and plassitic chick boxes (use 2% solution for Mycoptesma and Appsyllas filterus and 3% solution for Appsyllas filterus and 3% solution for Appsyllas filterus and 3% solution for Appsyllas filterus and an adjunct either VIRPOON 5 is recommended for use in logging fourt metrogic operations as an adjunct either

VIRRON S is recommended for use in logging (with misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRROM S at 1-2% solution is suitable. Fog (wet mist) until the area is most using automatic well foggers. according to manufacturer's use directions

BROILER/BREEDER HOUSES: Following removal of chickens, feed and water troughs remove menure and litter and spray floors and side walls with VIRICIN 5 at 1%. Thoroughly wash waterest and feeders with a 1% solution of VHRON S (use 2% solution for Mycoplasma and Aspergillus flewus and 3% solution for Aspergillus furnigetus). After contact for lan minutes, rime with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

CONTROLS: Bacterie of Streptoceccus pyopenes. Staphytoceccus aurius, Klebsiella pneumones, Escherichte colf, Salmosella hyphrmuram, Salmosella chelerassus, Pseudomonas aenajmosa, Staphytoceccus epidermidis, Mycoplasma gallisaptoum, Bordetella bronchisaptica. Paeteurella multiocida, Campylobacter pyteridis, Clostridium perfringens, Actinobacitus prorepneuments. Teponeme hydrosertome, Bordesste arium. Vinces; Hog cholors, Serie influenza, Porcing genvolrus, Rosevral danhos, Vescular somethis. Posedorebles, PRRS (Porcine Reproductive & Respiratory Syndrome). Alricen Seese Fever. Fungi, Aspergillus (lavus,

Appropria functions, Canddo albooms, Fusarum mentiones.

VIRIGON S is recommended for use in farrowing pens, weaner accomodation grower accomodation and processing plants: VIRIGON S at 1% solution is

generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and Aspengillas fleves and 3% solution for Aspengillas Fundatus). VIFRODN S is recommended for use in logging (well misting) operations or as an adjunct either preceding or tollowing regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable forg (well mist) until the area is most using automatic loggers according to

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until nurfaces are repiet. Allow at least 2 hours before entering area that has been fogged. VIRION S passes the AOAC gerelicidal and detergent sanitiser test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings and floors, spray at a

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Keep out of mech of children. Always replace lid other use. Wash emply container thoroughly and dispose





Virkon, S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

Streptococcus pyogenes. Campylobacter pyloridis. Klebsiella pneumoriae Escherichia coli, Salmonella typhimurium, Salmonella choleraeeuis, Pseudomonas serugmosa, Staphylococcus aureus, Staphylococcus epidermide Mycoptasma gallisepticum, Clostridium periringens, Bordetella avium. VIRUSES OF

Newcastle Disease. Infectious Bronchitis, Infectious Bursal disease Avan Laryngotracheibs. Avan Influenza, Marek's Deease, Egg Orop Syndrome. Duck Viral Entertils, Turkey Horpes Virus, African Swine Fever

Aspergillus Navus, Aspergibus furnigatus, Candida albicans.

ACTIVE INGREDIENTS

Polassium peroxymonosulfate	20.49
Sodium Chloride	1.59
INERT INGREDIENTS	78.19
TOTAL	100.09

Equivalent to 9 75% Available Chiorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Destributed by and manufactured for



Durvet Inc. Blue Springs, Mesoun, 64014-1-800-821-5570 Made in England by Antec International Limited

VIRIKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512





Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA

Streptococcus pyogenes. Stephylococcus aureus, Klebsielle pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraeeus. Pseudomones aeruginosa, Staphylococcus epidermidis, Mycoplasma gallisepticum, Bordetella bronchiseptica, Pasteurella multocida. Campylobacter pyloridis. Clostridium perlimgens, Actinobacilius pleuroprieumoniae, Treponema hyodysentenae, Bordetalia avium

Hog cholers. Swine influenza, Porcine pervoverus, Rotaviral diarrhea, Vasicular stomables, Pseudorables, PRRS (Porcine Reproductive & Respiratory Syndrome), African Swine Fever

FUNGI

Aspergillus flevus, Aspergillus furnigetus, Candida albicane, Fusarum moniliforma.

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed by and manufactured for



Durvet Inc. Blue Springs, Mesourt, 64014-1-800-821-5570 Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by Artice International Limited U.S. Patent No. 4822512

Virkon.S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American 1 gallon 10 gallons 50 gallons	1.3 ounces 13.4 ounces 66.8 ounces	2.7 ounces 26.7 ounces 133.5 ounces





For DISHMFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISHMFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Powder is corroane. Causes slon burns and irreversible eye damage Harmful if swallowed, absorbed through stan, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and nubber gloves. Avoid breathing dust. Wear goggles, too shletd, or safety glasses. Weath hands thronoughly with soop and water after handling. Remove contaminated clothing and wash before rause. Corrosive statement refers to powder only, not in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention. IF ON SKIN: Wash with plenty of sosp and water. Get medical attention of initiation persists.

IF INHALED or symptoms of coughing, choking, or wheazing are troublesome, remove to fresh air and seek medical attention. F SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

<u>HOTICE OF PHYSICIAM</u>: Probable mucosal damage may contraindicate the use of gentric tavage.



Manufactured for

Durvet Inc. Blue Springs, Missouri, 64014-1-800-821-5570

Made in England by Antac International Limited

EPA Reg. No. 82432-1-12281. EPA Est. No. 62432-EN-001

MAR 7 1996

Dr. Alan R. Wagner, D.V.M., M.S. Agent for Antec International Limited Chilton Industrial Estate Sudbury Suffolk C010 6XD England

Dear Dr. Wagner:

Subject: Virkon S

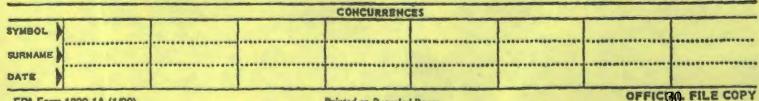
EPA Registration No. 62432-1

Your Amendment Dated August 8, 1995

This is in response to your amendment of revised master labeling for the subject product. Per our telephone conversation, this label amendment submission supercedes the ones dated April 11th and June 20th 1995.

The submitted labeling is not acceptable. It must be revised in accordance with the following comments and resubmitted for our review.

- Delete Campylobacter coli and Campylobacter jejuni. These are also human pathogens. Therefore, data are required.
- Delete Leptospirosis. This is the disease. 2.
- 3. Delete "Salmonella enteritidis". This is a human pathogen. Data are required.
- 4. Delete "Parainfluenza". This is a human pathogen. Data are required.
- Delete "Leukoencephalomalacia" and "Moldy corn 5. poisoning". These are diseases.
- Delete "Listeria monocytogenes". This is a human pathogen. Data are required.
- 7. Delete "Erysipelothrix rhusiopathiae. This a human pathogen. Data are required.
- Delete "Bovine viral diarrhea. This is a disease. 8.



EPA Form 1320-1A (1/90)

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*U.S. Government Printing Office: 1982 -- 620-856/40672

- Delete "Atrophic Rhinitis, Colibaciliosis, Enteritis, Mastitis, Necrotic Enteritis and Salmonellosis. These are diseases.
- Delete "Transmissible Gastroenteritis". This is a disease.
- Delete "Parainfluenza, Infectious hepatitis and Oral papillomatosis". These are diseases.
- Delete "Coronavirus, This is both a human and animal pathogen. Data are required.
- 13. Delete rabies. This is the disease.

All of the above pathogens and diseases must be deleted wherever they appear throughout the labeling.

14. This product has only been accepted for use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities.

Delete all references (delete p. 4) to use of this product in cleaning, sanitizing and disinfecting institutuional and food processing and service facilities. Efficacy data are required to support these uses. Also, the formulation must be cleared for use on food contact surfaces.

15. Delete all references (delete p. 5) to use of this product for the protection of hotel guests and ship passengers (virucide, bactericide, fungicide). No data has been submitted to support any of these claims.

Submit five (5) copies of revised labeling for our review.

If you have any questions concerning this letter, please call me at (703) 305-7964.

Sincerely yours,

2

Ruth Douglas Product Manager (32) Antimicrobial Program Branch Registration Division (7505C)

EOUINE BACTERIA Clostridial diarrhea Enteric Colibacillosis Fistulous Withers (Poll Evil) Taylorella equigenitalis Streptococccus equi (Strangles) Pseudomonas mallei (Glanders) Bordetella bronchiseptica Salmonella enteritidis **EQUINE VIRUSES** African Horse Sickness Equine Viral Arteritis (Pink Eye) Coital Exanthema Myeloencephalopathy Rhinopneumonitis Equine Infectious Anemia (Swamp Fever) Equine papillomatosis Equine Contagious Abortion Adenovirus Pneumonia -Equine Influenza (The Cough) -Parainfluenza > H E FUNGI

Antec International

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

Dermatophytosis (Ringworm) Dermetophylosis (Mud Fever) -Fus In moniliforme Leukoencephalomalacia Moldy Corn Poisoning **BOVINE BACTERIA** Listeria monocytogenes 14 Moraxella bovis Erysipelothrix rhusiopathiae Mycobacterium bovis Haemophilus somnus BOVINE VIRUSES Calf rotavirus Infective Bovine Rhinotracheitis

Bovine Viral Diarrhea

Adenovirus Type 4

Mouth Disease

NE FUNGI

Fusarium moniliforme

Rabies -

Pseudorabies

BACTERIA Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Salmonella enteritidis 7 H Pseudomonas aeruginosa Staphylococcus aureus -Mycoplasma gallisepticum

VIRUSES Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Candida albicans Avian Laryngotracheitis -Avian Influenza -Marek's Disease Egg Drop Syndrome Turkey Herpes Virus Duck Herpes Virus

FUNGI

Aspergillus flavus

Staphylococcus epidermidis Duck Viral Enteritis Clostridium perfringens < Bordetella avium ACTIVE INGREDIENTS Potassium peroxymonosulfato...... 20.4% Sodium Chloride..... 1,5%

INERT INGREDIENTS...... 78.1%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

SWINE BACTERIA Bordetella bronchiseptica Pasteurella multocida . -Campylobacter coli-Campylobacter jejuni Discon Atrophic Rhinitis Colibaciliosis Enteritis Mastitis Necrotic Enteritis Salmonellosis Erysipelothrix rhusiopathiae Leptospiresis Actinobacillus pleuropneumoniae Treponema hyodysenteriae Listeria monocytogenes 🔼 Clostridium perfringens SWINE VIRUSES Hog Cholera -Swine Influenza -Transmissible Gastroenteritis Porcine parvovirus Rotaviral diarrhea Vesicular stomatitis -Aspergillus fumigatus Pseudorabies -Porcine Reproductive and Respiratory Syndrome (PRRS) African Swine Fever Foot and Mouth Disease Rabies SWINE FUNGI

COMPANION ANIMALS BACTERIA

Fusarium moniliforme

Staphylococcus aureus -Streptococcus pyogenes ---Klebsiella pneumoniae Pseudomonas aeruginosa VIRUSES Canine Parvovirus Distemper 7 Rabies Parainfluenza Infectious hepatitis Oral papillomatosis Coronavirus HHA Leptospira canicola

Feline parvovirus Feline herpes. Feline calieivirus FUNGI .. . Microsporum canis -

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Palent No. 4822512

(2)

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Salmonella enteritidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium, Mycoplasma gallisepticum and Necrotic Enteritis.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Transmissable Gastroenteritis, Porcine Parvovirus, Vesicular Stomatitis, Pseudorabius, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, African Swine Fever, Foot and Mouth Disease and Rabies. Bacteria of Atrophic, Rhinitis, Colibaciliosis, Lepuspiresis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmoneilosis, Treponema hyodysenteriae Listeria monocytogenes and Clostridium perfringens. Fungi: Fusarium moniliforme.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION

APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

For Topical Use On Animal; Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day Repeat as necessary. Stables, Horse Boxes, Feed Rooms; Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand-sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases; By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonella entertidis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi; Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), Fusarium moniliforme, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Listeria monocytogenes, Moraxella bovis, Erysipelothrix rhusiopathiae, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

Virkon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. Virkon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hapatitis, Oral-papillomatosis, Coronavirus, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus.

Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.



FOR CLEANING, SANITIZING AND DISINFECTING INSTITUTIONAL AND FOOD PROCESSING AND SERVICE FACILITIES

Virkon S is recommended for use in food handling and food preparation areas of restaurants and food processing plants, and in: stores, factories, schools, hotels, offices, ships, planes, transportation terminals, supermarkets and food warehouses.

Virkon S is effective against wide range of viruses, bacteria and fungi including Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumonia, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum, Salmonella enteritidis, Listeria monocytogenes, Clostridium perfringens, Shigella sonnei, Aspergillus flavus, Candida albicans and Aspergillus fumigatus.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Virkon S passes the AOAC Germicidal and Detergent sanitizer tests at a concentration of 0.5% (1:200).

With Virkon S, only one product is needed to clean and sanitize or disinfect all surfaces.

Cleaning and Sanitizing Food Contact Surfaces. Remove gross dirt and wash surface with a 0.5% Virkon S solution prepared according to the table below. Apply to surface using a sponge, brush, or spray device until the surface is visibly clean. For non-porous surfaces, rinse and apply 0.2% solution to surface. Let stand 2 minutes and rinse with potable water. For porous surfaces, rinse and apply 0.6% solution to surface. Let stand 2 minutes and rinse with potable water.

Cleaning and Disinfecting Non-food Contact Surfaces. Remove gross dirt and prepare 1.0% Virkon S solution prepared according to the table below. Apply to surface using a mop sponge, brush, or spray device until the surface is visibly clean. Air dry. In cases of fungal or viral contamination of non-food contact surfaces, follow these instructions substituting a 2.0% Virkon S solution.

Sanitizing Toilet Bowls. After flushing, sprinkle Virkon S powder around the bowl, scrub with a brush, leave for 10 minutes. Flush.

DILUTION CHART

To this much water:	0.2% solution add this much VIRKON S (200ppm available Chlorine)	0.5% solution add this much VIRKON \$ (500ppm available Chlorine)	0.6% solution add this much VIRKON S (600ppm available Chlorine)	1% solution add this much VIRKON S (1000ppm available Chlorine)	2% solution add this much VIRKON 3 (2000ppm avaliable Chlorine)
American 1 gallon 10 gallons 50 gallons	0.3 ounces 2.6 ounces 13.4 ounces	0.7 ounces 6.7 ounces 33.4 ounces	0.9 ounces 7.8 ounces 40.2 ounces	1.3 ounces 13.4 ounces 66.8 ounces	2.6 ounces 28.4 ounces 133.6 ounces
Metric 10 litres 50 litres 200 litres	20 grams 125 grams 500 grams	50 grams 250 grams 1000 grams	60 grams 300 grams 1200 grams	188 ទានកាន 500 grams 2088 ទាងព្រទ	200 grams 1000 grams 4000 grams





VIRKON S FOR THE PROTECTION OF HOTEL GUESTS AND SHIP PASSENGERS

VIRUCIDE, BACTERICIDE, FUNGICIDE

INFECTIOUS SOURCE	THE DANGERS	CONTROL	VIRKON S
PEOPLE - from saliva.	Transmits bacteria and viruses including staphylococci and streptococci and herpes virus.	Clean and sanitize all crockery, cuttery and drinking glasses with Virkon S solution. Also containers in which crockery etc is transported. Change frequently.	Use 0.5% Virkon S to clean and sanitize. Rinse in water.
PEOPLE - from poor personal hygiene and from surfaces in tollets, wash basins, etc.	Transmits bacteria and viruses causing enteritis, dysentery and typhoid.	Clean and disinfect all surfaces in the bathroom twice daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect. Rinse in water
PEOPLE - lungal foot infections.	Athletes toot intections in swimming pool changing areas, bathroom floors.	Clean and disinfect floors daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect.
PEOPLE - Nursery play areas	From young children where personal hygiene is poor - contaminating equipment and play areas.	Clean and disinfect play areas and equipment twice daily with Virkon S.	Use 1.0% Virkon S to clean and disinfect. Rinse in water.
PEOPLE - Blood, body fluids, vomit.	All blood should be treated as HIV positive; vornit and body fluids are also highly injective.	Cover heavy blood splllage with Virkon S powder. Leave for 10 minutes, then sooop into plastic bag.	Use 1.0% Virkon S to clean and disinfect area.
FOOD PREPARATION AREA - from Poultry, Meat, Fish, Cheese	From contamination by Salmonella, Listeria monocytogenes, Escherichia coli, Shigella sonnei, Campylobacter	Clean and sanitize all surfaces and equipment on which food is prepared with Virkon S 3 or 4 times daily. Clean and sanitize cheese boards, containers regularly.	Use 0.5% Virkon S to clean, Rinse. Apply 0.2% solution and let stand 2 minutes. Rinse with potable water.
REA	From vegetables contaminated with soil containing organisms of human and animal fecal origin.	Clean and sanitize all surfaces in this area - including sinks, work benches, floors, containers in which vegetables pass to kitchen.	Use 0.5% Virkon S to clean. Rinse. Apply 0.2% solution and let stand 2 minutes. Rins with potable water.
FOOD - Preparation in the kitchen	Infection from all surfaces: benches, mixing bowls, equipment used for preparing cold items, cream, mayonnaise and cutting meat for cold buffet etc. Contamination as above.	Clean and sanitize with Virkon S solution regularly - several times daily and between different foods,	Use 0.5% Virkon S to clean. Rinse. Apply 0.2% solution and let stand 2 minutes. Rins with potable water.
WASTE FOOD BINS	Contamination as above.	Clean and disinfect daily with Virkon S solution.	Use 1.0%-Virkon S to clean and disinfect. Rinse in water.
BARS/RESTAURANTS - Crockery, cutlery, drinking glasses in restaurants and bars and in the trays in which they are transported.	From people who transmit viral and bacterial contaminants from saliva and hands.	Clean and sanitize. Wash all splasses etc in Virkon S solution.	Use 0.5% Virkon S to clean and santize. Ainse in water. Change Virkon S solution tequently.

N.B. Where dishwashing/pot washing machines are available, if properly operated, the items should be sterile when they leave this machine. At this stage they are open to contamination from people and surfaces; for this reason all surfaces and equipment in the known food processing zone should be washed with Virkon S. This single operation will clean and sanitize thus preventing the spread of infection and contamination which occurs when cleaning is done using a detergent only.



BACK PANEL DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125 g	6 oz	
100 g	5 oz	The measure cap holds when filled
75 g	4 oz	level 500 g or 17.5 ounces.
50 g	3 oz	
	2 oz	Brim full - contains 200 g or 17 ounces.
	l oz	

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Powder is corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Corrosive statement refers to powder only not in use solution.

PRACTICAL TREATMENT

IF IN EYES: Hold cyclids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose in in trash. Do not mix this product with other chemicals.

ANTEC INTERNATIONAL LTD Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England Tel: (1787 77305 Telx; 987495 Fax: (1787) 310846

EPA Est. No. 62432-EN-00

EPA Reg. No. 62432-1

8-10-95 0 pp # 228/84

FRONT END PROCESSING APPLICATION INFORMATION CHECK

PM 33			
EPA COMPANY NUMBER (2432-	/		
EPA REGISTRATION NUMBER STATUS (For Amendments)	Active	Cancelled	
	Not i	n REFS	
"ME-TOO" CITED PRODUCT STATUS	Active	Cancelled	
	Not	in REFS	
PRAT RECORD CREATED			

AMENDHENT

	·	BANH 328184
	PAST TRACK * APPLICATION FOR AME	,
WITH DATA	Init. Date	NO DATA Init. Date
FEU		FEU few 8-10-9
SIG (DATA)		PM
FEU		
PM		
	REGULAR APPLICATION FOR AMI	ENDKENT
WITH DATA	Init. Date	NO DATA Init. Date
FEU		FEU
SIG (DATA)		PM

Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

08/10/95

ALAN WAGNER DR ALAN WAGNER, DVM, MS 2304 ANHINGA DR KISSIMMEE FL 34743

CFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S

COMPANY NAME: DR ALAN WAGNER, DVM, MS

OPP IDENTIFICATION NUMBER: 228184 EPA REGISTRATION NUMBER: 62432-1

EPA RECEIPT DATE: 08/10/95

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

J. Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division

DR. ALAN R. WAGNER
Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2304 Anhinga Drive Kissimmee, Florida 34743 Ph: 407/344-9803 Fax: 407/344-9980

August 8, 1995

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
Room 278 Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Subject: VIRKON S (EPA Reg. # 62432-1)

Master Label Update

Dear Ms. Douglas:

Please find enclosed for your review "Application For Pesticide Amendment" updating our EPA Master Label for VIRKON S.

In reference to the previous Master Label Amendment submitted to you on June 20, 1995, I would appreciate your review of the enclosed amendment update, Ms. Douglas, which I hope can be attached to the June 20, 1995 submisson so as to expedite the review and approval process.

The enclosed Master Label Amendment concerns an updated section identifying the use of VIRKON S for cleaning, sanitizing and disinfecting institutional and food processing and service facilities.

I do want to thank you for your excellent cooperation, assistance and courtesy extended to me by you and your staff regarding our EPA regulatory affairs activities. Looking forward to seeing you again soon.

Sincerely,

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd.

ARW/mw

Enclosures

42

5. Date

August 8, 1995

4. Typed Name

Alan R. Wagner, D.V.M., M.S.

SEPA.	Environmenta Washi	Inited States I Protection ngton, DC 20466	Agency		Registration Amendme Other	on	OPP Identifier Number 228184
No		Application	for Pesticide		1	la p.	prosed Classification
1. Company/Product Numbe	r		2. EPA Prod	uct Manager		S. PR	
4. Company/Product (Name)			PM#			_	None Restricted
5. Name and Address of App	plicant <i>linclude ZIP Co</i>	de)		No			FIFRA Section 3(c)(3) mposition and labeling
			Section - II			/	
Resubmission in resp Notification - Explain Explanation: Use addition	`		01	le Too" Applic			
			Section - Mi				
1. Material This Product Wil	l Be Packaged In:						
Child-Resistant Peckaging Yes* No **Certification must ubmitted**	Unit Packaging Yes No If "Yes" Unit Packaging wgt	No. per container	Yes No If "Yes" Package wgt	No per container	F	Aetal Plastic Slass Paper	Specify)
3. Location of Net Contents	Information	4. Size(s) Retai	Container	IB LO	cation of Label	Directio	ons
	Container	1, 512 (3) 116(6)	Container	A	On Label		panying product
6. Manner in Which Label is		Lithogra Paper pl Stencile	ph ued	Other			parting process
	/	- Contono	Section - IV		1		
1. Contact Point (Complete	items directly below	for identification	of individual to be co	ntacted, if ne	essary, to produ	ess this	application.)
Name		Т	ītie		Te	Helphon	e No. (Include Area Code)
	ements I have made or ny knowingly false or t law.		attachments theret			ete.	Date Application Received (Stamped)
2. Signature		3.	. Title				
4. Typed Name		5.	. Data				43
EPA Form 8670-1 (Rev. 8-94	1) Previous editions er	e obsolete.		White - E	PA File Copy to	riginal)	Yellow - Applicant Copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Polloy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only, Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5, Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner In which label is affixed to product Indicated the method product label is attached to retail container.

<u>SECTION IV</u> (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

SEPA Environmental Protection Washington, DC 204						Registration Amendment Other		OPP Identifier Number		
		Application	on for P	estici	de - Sec	tion				
1. Company/Product Number	or -	N		2. EPA	Product Man	ager	401	3. P	roposed Class	ification
4. Company/Product (Name			3	PM#	- 11			7	None	Restricted
5. Name and Address of Ap	plicant (Include ZIP Co.	de)		(b)(i), n to: EPA F					FIFRA Secomposition a	
			Sect	ion -				-/		
Notification - Explain Explanation: Use additio			on I and Sec	etion II.)	"Me Toe" / Other - Exp		/ .			
The second second			Sont	ion - l	0					
1. Material This Product Wi	ll Be Packaged in:		3600	OII - A						
Child-Resistant Packaging Yes* No Partification must Submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per container	ID	Yes No	No. per contains	ď	2. Type of	Metal Plastic Glass Paper	Specify)	
3. Location of Net Contents	Information	4. Size(s) Re	tail Contain	er		5, Lo	cation of Lab		ons	
Label	Container	1/30					On Labe		mpanying pro	duct
6. Manner in Which Label is	Affixed to Product	Litho	graph glued cifed		Othe	r	1			
				on - I	V		1			
1. Contact Point Complete	items directly below f	or identificati	on of individ	dual to b	e contacted,	if nec	essary, to pr	obess this	s application.	1
Name	/		Title				,	Telephor	ne No. (Includ	le Area Code)
	ements I have made on ny knowingly false or n law.		all ettache					The state of the s	6 Date Ap Received	
2. Signature			3. Title							1
4. Typed Name			5. Date					-		1

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- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
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1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, past or crop (specify)"; "amend the Confidential Statement of Formula by..."; "eregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
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- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," raregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

Submission No. 5489716 Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 62432-1 PM 3Z Action Code 301 10 Descriptor (Amend/Resubmissions only) Updated Master Label |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / /(C) Certification Packaging / / (N) No /(S) Service Person |20| Registration Type: / (R) Non-residential Use Only (1) Conditional (2) Unconditional / (N) Not-Applicable 25 Proposed Classification: |30 | Final Classification: // (R) Restricted // (R) Restricted (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: 40 Date Received by PM 10 16 210 9 15 1 0 16 2 16 9 15 10 17 0 15 9 15 [80] Method of Support: (1) Cite-All (6) Owner Submission. // (4) Not Applicable // (7) Total Submission // (5) Not Submitted // (8) Selective Method DATE DUE DATE RESPONSE RESPONSE Reviewers Requested: SENT DATE RETURNED CH EF PL DEB NDEB TB EEB EFGB 1115 FINAL |120| Response

47

m Clark

Reviewer ID



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

06/27/95

ALAN WAGNER DR ALAN WAGNER, DVM, MS 2304 ANHINGA DR KISSIMMEE FL 34743

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S

COMPANY NAME: DR ALAN WAGNER, DVM, MS

OPP IDENTIFICATION NUMBER: 191008 EPA REGISTRATION NUMBER: 62432-1

EPA RECEIPT DATE: 06/26/95

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

A. Wrice

Front End Processing Staff Information Services Branch

Program Management and Support Division

DR. ALAN R. WAGNER

Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2304 Anhinga Drive Kissimmee, Florida 34743

Ph: 407/344-9803 Fax: 407/344-9980

June 20, 1995

Ms. Ruth G. Douglas (PM32) Antimicrobial Program Branch Registration Division (7505C) U.S. Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460

Subject: VirKon S (EPA Reg # 62432-1)

Master Label Update

Dear Ms. Douglas:

Please find enclosed for your review "Application For Pesticide Amendment" updating our EPA Master

We have responded to your letter of May 5, 1995 and modified the updated Master Label by identifying the specific bacteria on the label and revised the name of record of the product as Virkon S by deleting the Virkon E identification. This revision was sent to you on May 24, 1995 to the attention of Ms. Marianne Clark as requested.

At this point, Ms. Douglas, I would appreciate your review of the enclosed Master Label Amendment and updates, hopefully for inclusion or attachment to the previous submissions of Master Label Amendments (June 24, 1994/Fast Track, April 11, 1995 and May 24, 1995) so as to expedite your review and approval

In am planning a Washington, D.C. trip in the very near future and will contact you to arrange an appointment to discuss our regulatory affairs activity and progress concerning our registration and reregistration efforts

Again, Ms. Douglas, thank you for your excellent assistance and courtesy extended to me regarding our regulatory concerns.

Sincerely,

alan R. Wagner Alan R. Wagner, D.V.M., M.S.

Agent for Antec International Ltd

ARW/mw

Enclosures

EQUINE BACTERIA

Clostridial diarrhea

Enteric Colibacillosis

Fistulous Withers (Poll Evil)

Taylorella aquigenitalis

Streptococcus equi (Strangles)

Pseudomonas mallei (Glanders)

Bordetella bronchiseptica

Salmonella enteritidis

EQUINE VIRUSES

African Horse Sickness

Equine Viral Arteritis (Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Infectious Anemia (Swamp Fever)

Equine papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

Parainfluenza

EQUINE FUNGI

Dermatophytosis (Ringworm)

Dermetophylosis (Mud Fever) Fus an moniliforme

Leukoencephalomalacia Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes

Moraxella bovis

Erysipelothrix rhusiopathiae

Mycobacterium bovis

Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Bovine Viral Diarrhea

Bovine Adenovirus Type 4

Pseudorabies

Mouth Disease Æ FUNGI

Fusarium moniliforme

Antec

International

(Virkon logo)

VIRKON® S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae

Escherichia coli

Salmonella typhimurium Salmonella choleraesuis

Salmonella enteritidis

Staphylococcus aureus

Clostridium perfringens

Bordetella avium

Pseudomonas aeruginosa

Mycoplasma gallisepticum

Staphylococcus epidermidis

VIRUSES

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease

FUNGI

Aspergillus flavus

Candida albicans

Avian Laryngotracheitis

Avian Influenza

Marek's Disease Egg Drop Syndrome

Turkey Herpes Virus Duck Herpes Virus

Duck Viral Enteritis

ACTIVE INGREDIENTS

701110	
Potassium peroxymonosulfato	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	78.1%
TOTAL1	00.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England

Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

SWINE BACTERIA

Bordetella bronchiseptica

Pasteurella multocida

Campylobacter coli

Campylobacter jejuni

Atrophic Rhinitis

Colibaciliosis

Enteritis

Mastitis

Necrotic Enteritis

Salmonellosis

Erysipelothrix thusiopathiae

Leptospirosis

Actinobacillus pleuropneumoniae

Treponema hyodysenteriae

Listeria monocytogenes

Clostridium perfringens

SWINE VIRUSES

Hog Cholera

Swine Influenza

Transmissible Gastroenteritis

Porcine parvovirus

Rotaviral diarrhea

Vesicular stomatitis

Aspergillus fumigatus Pseudorabies

Porcine Reproductive and

Respiratory Syndrome (PRRS) African Swine Fever

Foot and Mouth Disease

Rabies

SWINE FUNGI

Fusarium moniliforme

COMPANION ANIMALS BACTERIA

Staphylococcus aureus

Streptococcus pyogenes Klebsiella pneumoniae

Pseudomonas aeruginosa

VIRUSES

Canine Parvovirus

Distemper

Rabies

Parainfluenza

Infectious hepatitis

Oral papillomatosis

Coronavirus

Leptospira canicola

Feline parvovirus

Feline herpes

Feline calicivirus

FUNGI....

Microsponim canis



VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Palery No. 4822512



SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Marek's Disease, Egg Drop Syndrome, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter pyloridis, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Salmonella enteritidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium, Mycoplasma gallisepticum and Necrotic Enteritis.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

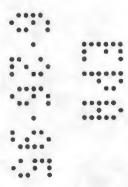
HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

VIRKON S passes the AOAC germicidal and detergent sanitizer test at a concentration of 0.5% (1:200) in the presence of 200 ppm hard water.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Swine influenza, Transmissable Gastroenteritis, Porcine Parvovirus, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, African Swine Fever, Foot and Mouth Disease and Rabies. Bacteria of Atrophic Rhinitis, Colibaciliosis, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis, Treponema hyodysenteriae, Listeria monocytogenes and Clostridium perfringens. Fungi: Fusarium moniliforme

VTRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VTRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH

FOR CLEANING AND DISINFECTING STABLES, EQUIPMENT AND AERIAL DISINFECTION APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one VIRKON S sachet to one gallon of warm water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonella enteritidis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi (Strangles) and Pseudomonas mallei (Glanders). Fungi; Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), Fusarium moniliforme, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Listeria monocytogenes, Moraxella Bovine Erysipelothrix rhusiopathiae, Haemophilus somnus and Mycobacterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

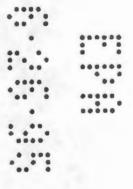
VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities.

VirKon S at 1% solution is generally suitable for cleansing and disinfection.

SIDE PANEL CONTINUED

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, Leptospira canicola, Feline parvovirus, Feline herpes and Feline calicivirus. Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis.



BACK PANEL

VIRKON. S

DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125g	6oz	
100g	50z	
75g	4 oz	
50g	3oz	
•	2oz	
	1oz	

Brim full - contains 200g or 7 ounces The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse. Refers to powder form only and not use-dilution.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

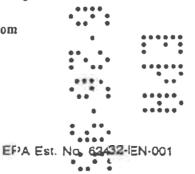
IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk C010 6XD, England
Tel: (1787) 77305 Telx: 987495 Fax: (1787) 310846

EPA Reg. No. 62432-1



Alan R. Wagner, D.V.M., M.S.

June 20, 1995

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERNORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use raregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling; 5. Three copies of any data submitted; 6. Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

- SECTION I This section must be completed, as applicable, for all registration actions.

 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PN number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing

address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III: "Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

12 Type of Packeging - Check the appropriate block if your product will be packaged in the indicated packaging types.

Indicate the size of the individual packets and number per retail container.

Indicate the size of the individual packets and number per retail container.

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Indicate the size of the individual packets and number per retail container. Location of Net Contents - Specify the net contents of all retail containers for your product.

4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.

5. Updation of Use Directions - Indicate the location of the use directions for your product.

be dermer in which tabel is affixed to product - Indicate the method product tabel is attached to retail container.

SECTION IV. CCOntact Point) - This Section must be completed for all applications for Registration actions (ige., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory. 6. EPA Use Only.

Reviewer ID Deaglas
Submission No. 5486847
Data Package No.
CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS
File Symbol/Reg. No. 6243d-1 PM 32 Action Code 300
10 Descriptor (Amend/Resubmisions only) Amended 2.be/
5 Intrastate Call-in / (Y) Yes 15 Child-resistant / (C) Certification Packaging
/_/ (N) No
20 Registration Type: [7] (R) Non-residential Use Only
(1) Conditional (2) Unconditional (N) Not-Applicable
25 Proposed Classification: 30 Pinal Classification:
(R) Restricted (R) Restricted
(G) General (N) Not Classified
Date on Application: 04 EPA Received Date: 40 Date Received by PM 014 119 5 014 18 9 5 014 21 9 5 MO DAY YR MO DAY YR
80 Method of Support:
[(1) Cite-All [(6) Owner Submission.
[(4) Not Applicable [(7) Total Submission
(5) Not Submitted (8) Selective Method
Reviewers Requested: DATE DUE DATE RESPONSE RESPONSE CH DATE RETURNED CODE DATE
EF
PL
DEB
NDEB
TB
EEB
EFGB
115 FINAL Response 120 Response 1495 ACTION Code 37 Superceded by MO DAY YR 75-DAY RESPONSE DUE DATE: LIVY Yes [IN) No 57

DR. ALAN R. WAGNER

Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2304 Anhinga Drive Kissimmee, Florida 34743 Ph: 407/344-9803 Fax: 407/344-9980

April 11, 1995

Ms. Ruth G. Douglas (PM32) Antimicrobial Program Branch Registration Division (7505C) U.S. Environmental Protection Agency 401 M Street S.W Washington, D.C 20460

Subject. VirKon S (EPA Reg. # 62432-1)

Dear Ms. Douglas:

Please find for your review "Application For Pesticide Amendment" updating our EPA Master Label, approval date December 1, 1994.

We have highlighted the modifications on the updated Master Label as you requested and have submitted 5 draft labels reflecting the modifications.

Again, I wish to thank you for your excellent assistance and courtesy extended to me concerning our regulatory affairs activities.

Anxious to see you soon during my next visit to your agency.

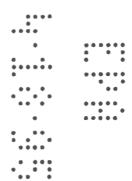
Sincerely,

acan

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd.

ARW/mw

Enclosures



EOUNE BACTERIA

Clostridial diarrhea

Salmonellosis

Enteric Colibacillosis

Fistulous Withers (Poll Evil)

Taylorella equigenitalis

Strangles

Glanders

Listeria monocytogenes

Bordatella bronchiseptica

Streptococcus equi

Salmonella enteritidis

EQUINE VIRUSES African Horse Sickness

Equine Viral Arteritis (Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Infectious Anemia (Swamp Fever)

Equine Papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

Rhinitis

Para enza

EQUINE FUNGI

Dermatophytosis (Ringworm) Dermatophylosis (Mud Fever)

Fusarium moniliforme

Leukoencephalomalacia

Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes

Moraxella bovis

Erysipelothrix rhusiopathiae

Mycobacterium bovis

Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Bovine Viral Diarrhea

Rabi

Bovine Adenovirus Type 4

Pseudorabies

Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

Antec International

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

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Klebsiella pneumoniae Escherichia coli

Salmonella typhimurium

Salmonella choleraesuis

Salmonella enteritidis

Pseudomonas aeruginosa

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Clostridium perfringes

Bordetella avium

VIRUSES

Newcastle Disease

Infectious Bronchitis

Avian Laryngotracheitis

Avian Influenza

Marek's Disease

Egg Drop Syndrome

Turkey Herpes Virus

Duck Herpes Virus

Staphylococcus epidermidis Duck Viral Enteritis

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FUNGI

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Bordatella bronchiseptica

Pasteurella multocida.

Campylobacter Spp.

Erysipelothrix rhusiopathiae

Leptospira Spp.

Actinobacillus pleuropneumoniae

Treponema hyodysenteriae

Listeria monocytogenes

Clostridium perfringes

SWINE VIRUSES

Hog Cholera

Swine Influenza

Transmissible Gastroenteritis

Porcine parvovirus

Rotaviral diarrhea

Vesicular stomatitis

Pseudorabies

Porcine Reproductive and

Respiratory Syndrome(PRRS)

African Swine Fever

Rahies

SWINE FUNGI

Fusarium moniliforme

ACTIVE INGREDIENTS

Potassium peroxymonosulfate...... 20.4% Sodium Chloride...... 1.5% INERT INGREDIENTS...... 78.1%

TOTAL100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

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U.S. Patent No. 4822512

SIDE PANEL

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Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter plyoridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Salmonella enteritidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium, Mycoplasma gallisepticum and Necrotic Enteritis.

DIRECTIONS FOR USE

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POULTRY PRODUCTION/RATITE PRODUCTION

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HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibaciliosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) Aspergillus flavus, Aspergillus fumigatus and Candida albicans.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

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EQUINE PRODUCTION APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi, Mycotoxic Disease, Pasteurella, Strangles and Glanders. Fungi; Dermatophytosis (Ringworm), Dermatophylosis (Mud Fever), Fusarium moniliforme, Leukoencephalomalacia, and Moldy corn poisoning.

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CONTROLS: Viruses of Calf rotavirus, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Listeria monocytogenes, Moraxella bovis, Erysipelothrix rhusiopathiae, Haemophilus somnus and Mycobecterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities VirKon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, and Leptospira canicola; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas acruginosa; Fungi of Microsporum canis. Viruses of Feline parvovirus, Feline herpes and Feline calicivirus.

BACK PANEL

VIRKON. S

DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
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1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
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10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
108-	800	
125g	6oz	
100g	50Z	
750	4 02	
50g	302	
	202	
	1oz	

Brim full - contains 200g or 7 ounces The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air acceptance medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk C010 67CD, England
Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

EOUINE BACTERIA

Clostridial diarrhea

Salmonellosis

Enteric Colibacillosis

Fistulous Withers (Poll Evil)

Taylorella equigenitalis

Strangles Glanders

Listeria monocytogenes

Bordatella bronchiseptica

Streptococcus equi

Salmonella enteritidis

EQUINE VIRUSES

African Horse Sickness Equine Viral Arteritis (Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Infectious Anemia (Swamp Fever)

Equine Papillomatosis

Equine Contagious Abortion

Adenovirus Pneumonia

Equine Influenza (The Cough)

Rhinitis

Paral enza

EQUINE FUNGI

Dermatophytosis (Ringworm)

Dermatophylosis (Mud Fever)

Fusarium moniliforme

Leukoencephalomalacia

Moldy Corn Poisoning

BOVINE BACTERIA

Listeria monocytogenes

Moraxella bovis

Erysipelothrix rhusiopathiae

Mycobacterium bovis

Haemophilus somnus

BOVINE VIRUSES

Calf rotavirus

Infective Bovine Rhinotracheitis

Wiral Diarrhea Rabie

Bovine Adenovirus Type 4

Pseudorabies

Foot & Mouth Disease

BOVINE FUNGI

Fusarium moniliforme

Antec International

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes Campylobacter plyoridas Klebsiella pneumoniae

Escherichia coli

Salmonella typhimurium Salmonella choleraesuis

Salmonella enteritidis

Pseudomonas aeruginosa

Staphylococcus aureus Staphylococcus epidermidis Duck Viral Enteritis

Mycoplasma gallisepticum Clostridium perfringes

Bordetella avium

VIRUSES

Newcastle Disease Infectious Bronchitis

Infectious Bursal Disease Candida albicans

Avian Laryngotracheitis

Avian Influenza

Marek's Disease

Egg Drop Syndrome

Tuckey Herpes Virus **Duck Herper Virus**

FUNGI

Aspergillus flavus Aspergillus fumigatus

ACTIVE INGREDIENTS

Polassium peroxymonosulfate...... 20.4% Sodium Chloride...... 1.5% INERT INGREDIENTS...... 78.1% TOTAL.....100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England

Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SWINE BACTERIA

Pasteurella multocida.

Campylobacter Spp.

Leptospira Spp.

Bordatella bronchiseptica

Erysipelothrix rhusiopathiae

Treponema hyodysenteriae

Transmissible Gastroenteritis

Listeria monocytogenes

Clostridium perfringes

SWINE VIRUSES

Porcine parvovirus

Rotaviral diarrhea

Vesicular stomatitis

African Swine Fever

Fuserium moniliforme

SWINE FUNGI

Porcine Reproductive and

Respiratory Syndrome(PRRS)

Hog Cholera

Pseudorabies

Rabies

Swine Influenza

Actinobacillus pleuropneumoniae

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, Avian Influenza, Turkey Herpes Virus and Duck Viral Enteritis. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter plyoridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Salmonella enteritidis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella avium, Mycoplasma gallisepticum and Necrotic Enteritis.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of

1%.

SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibaciliosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) Aspergillus flavus, Aspergillus fumigatus and Candida albicans.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION APPLICATIONS

For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever), Adenovirus Pneumonia, Parainfluenza, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Taylorella equigenitalis, Bordetella bronchiseptica, Streptococcus equi, Mycotoxic Disease, Pasteurella, Strangles and Glanders. Fungi; Dermatophytosis (Ringworm), Dermatopyhlosis (Mud Fever), Fusarium moniliforme, Leukoencephalomalacia, and Moldy corn poisoning.

BOVINE PRODUCTION

CONTROLS: Viruses of Californius, Infectious Bovine Rhinotracheitis, Bovine Viral Diarrhea, Rabies, Bovine Adenovirus Type 4 and Pseudorabies; Bacteria of Listeria monocytogenes, Moraxella bovis, Erysipelothrix rhusiopathiae, Haemophilus somnus and Mycobecterium bovis; Fungi of Fusarium moniliforme.

DIRECTIONS FOR USE

VirKon S is recommended for use in areas associated with bovine stabling, quarantine or feedlot facilities. VirKon S at 1% solution is generally suitable for cleansing and disinfection.

COMPANION ANIMALS

CONTROLS: Viruses of Canine Parvovirus, Distemper, Rabies, Parainfluenza, Infectious hepatitis, Oral papillomatosis, Coronavirus, and Leptospira canicola; Bacteria of Staphylococcus aureus, Streptococcus pyogenes, Klebsiella pneumoniae, and Pseudomonas aeruginosa; Fungi of Microsporum canis. Viruses of Feline parvovirus, Feline herpes and Feline calicivirus.

VIRKON. S

DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125g	6oz	
100g	50Z	
75g	4 02	
50g	3oz	
	2oz	
	toz	

Brim full - contains 200g or 7 ounces The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD
Windham Road, Chilton Industrial Estates
Sudbury Suffolk C010 600, England
Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

(A)			TITL WARRANGO.	OMB No. 2070-	0060, Approval expires 11-30-93
(A) SEP	United States Environment Office of Pesticide Pro Washington, D Application 1	ograms (H7505C)	х	Registration Amendment Other	
	Se	ection I			
1. Company/Product Numb	er e	2. EPA Proc	luct Manager	3	Proposed Classification
62432		Ms. Ru	th G. I	ouglas	None Restricted
4. Company/Product (Name	9)	PM#			None Restricted
VirKon S		32			
Sudbury, Suff		(b)(i), my p to:	roduct is sim		with FIFRA Section 3(c)(3) in composition and labeling
	Sec	tion I I			
Amendment - Explain Resubmission in respo	below onse to Agency letter dated	Final (Agen	printed labels i cy letter dated oo" Application	n.	
Material This Product \ Child-Resistant Packaging	Section Sectin Section Section Section Section Section Section Section Section	on III Water Soluble Packs	eging	2. Type of Cont	ainer
Yes* No	Yes X No	Yes X No		Met X Plas	al tic
Certification must be submitted.	If "Yes," No. per Unit Package wgt. container	If "Yes," Package wgt.	No. per container	1	er (Specify)
3. Location of Net Contents			1 = 1		V
	Container	Retail Container	JE	On Labeling a	Directions
6. Manner In Which Label I	container s Affixed To Product Paper Stend	graph X r glued iled	JE	On Labeling a	
6. Manner In Which Label I	container s Affixed To Product Paper Stend	graph X r glued iled tton IV	Other (P	On Label On Labeling a	ccompanying product
Manner In Which Label I Contact Point (Complete Name	container s Affixed To Product Paper Stence settems directly below for identification	graph r glued iled itlon IV n of individual to be con Title Manager, Affairs Agent for A	Other (P	On Label On Labeling a ressure essary, to processory Ory 40	sensitive) statis application statis application change No. (Include Area Code) 7/344-9803
6. Manner In Which Label I 1. Contact Point (Complete Name Alan R. Wagne	Sectification to I have made on this form and all a knowingly false or misleading statem.	graph r glued siled ttlon IV n of individual to be con Title Manager, Affairs Agent for A n attachments thereto are	Other (P	On Label On Labeling a ressure	ccompanying product Sensitive) s this application phone No. (Include Area Code) 7/344-9803
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6. Manner In Which Label I 1. Contact Point (Complete Name Alan R. Wagne I certify that the statement acknowledge that any both under applicable land). 2. Signature	Section of the sectio	graph r glued illed itlon IV or of individual to be con Title Manager, Affairs Agent for A n attachments thereto are nent may be punishable 3. Title Manager, Re	ntacted, if necessary in the control of true, accurate by fine or imagulator	On Label On Labeling a ressure essary, to process ory ternation e and complete, prisonment or	sensitive) sensitive) sthis application phone No. (Include Area Code) 7/344-9803 6. Data Application Received (Springed)
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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERMORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PN-223, U.S. Environmental Protection Agency, 401 M Street, SM, Weshington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4); 3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling; 5. Three copies of any data submitted:

Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned
 to you as a besic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Humber.
- 2. EPA Product Nameger If known, fill in the name and PM number of the EPA Product Nameger.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief
...explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the
Confidential Statement of Formula by..."; "reregistration submission": separal label according to the submission of the submissio Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments. of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types.

Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.

3. Location of Net Contents - Specify the net contents of all retail containers for your product. 4. Size(s) of Retail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the Location of the use directions for your product.

6. Hanner in which tabel is affixed to product - Indicate the method product tabel is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Only.

			Reviewer ID	mo	Clark
			Submission 1	No. 54	198165
			Data Package	No	
CODING FORM FOR APPLICAT	IONS FOR REC	ISTRATIO	N/AMENDMENTS		
File Symbol/Reg. No.	2432-1	PH 3	2 Actio	on Code 30	_
10 Descriptor (Amend/Re	sumisions	only)	mended.	apple -	revision
5 Intrastate Call-in	(Y) Y	es 15	Child-resistar Packaging	it //(c)	Certification
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20 Registration Type:					Non-residential Use Only
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(G) General		N) Not C	lassified		
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Reviewers Requested:	DATE	DATE	DATE RETURNED	RESPONSE	RESPONSE DATE
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DEB					
NDEB	-				
TB					
EEB					
EFGB					
TIS FINAL Response ACTION Code	17		120 Response	DEQ1	1 1995

DEC 11 1995

Dr. Alan R. Wagner, D.V.M., M. S. Agent for Antec International Limited 2821 River Park Drive Columbus, OH 43220

Dear Dr. Wagner:

Subject: Virkon S

EPA Registration No. 62432-1

Your Resubmission Dated May 24, 1995

This is in response to your resubmission of revised labeling for the subject product.

The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provided that you make the following revisions before you release the product for shipment bearing the amended labeling.

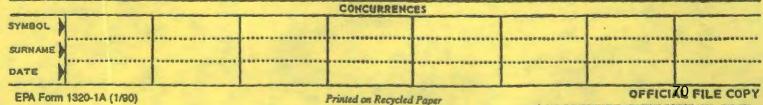
- 1. Delete "Leptospirosis". This is the disease and not the name of the organism.
- 2. Delete "Campylobacter coli" and "Campylobacter jejuni."
 These are also human pathogens. Therefore data would
 be required.

A stamped copy is enclosed for your records. Submit one copy of the final printed label.

If you have any questions about these comments, please call Marianne Clark at (703) 305-7879.

Sincerely yours,

Ruth Douglas Product Manager (32) Antimicrobial Program Branch Registration Division (7505C)



☆ U.S. GOVERNMENT PRINTING OFFICE 1995 - 619-457

EQUINE BACTERIA

Clostridial diarrhea

Salmonellosis

Enteric Colibacillosis

Fistulous Withers (Poll Evil)

Taylorella equigenitalis,

Strangles

Glanders

EQUINE VIRUSES

African Horse Sickness

African Viral Arteritis (Pink Eve)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Contagious Abortion

Equine Papillomatosis

Equine Infectious Anemia (Swamp Fever) For Use in Cleaning and Disinfecting Industrial

Adenovirus Pneumonia

Equine Influenza (The Cough)

EQUINE FUNGUS

Dermatophytosis (Ringworm)

Dermatophylosis (Mud Fever)

BACTERIA

Streptococcus pyogenes Campylobacter pyloridis Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphyloccoccus epidermidis Mycoplasma gallisepticum

Clostridium perfringes

Antec International

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

Animal and Agricultural Facilities

EFFECTIVE AGAINST:

VIRUSES OF

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease

Avian Laryngotracheitis Avian Influenza Marek's Disease Egg Drop Syndrome

ACTIVE INGREDIENTS

Potassium perexymonosulfate	20.49
Sodium Chloride	1.5%
INERT INGREDIENTS	78.1%
TOTAL1	00.076

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England

Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited

SWINE BACTERIA

Bordetella bronchiseptica Pasteurella multocida Campylobacter coli Carapylobacter jejuni Ervsipelothrix rhusiopathiae,

Leptospiresis-Actinobacillus pleuropneumoniae

Treponema hyodysenteriae.

SWINE VIRUSES

Hog cholera Swine influenza TGE, Blue eye Porcine parvovirus Rotaviral diarrhea Vesicular stomatitis **Pseudorabies**

FUNGI

Aspergilius flavus Candida albicana



SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, and Avian Influenza. Fungi (molds and veasts) - Aspergillus flavus and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter plyoridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis. Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

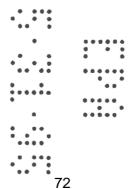
ATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma and Aspergillus flavus).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and Aspergillus flavus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Poot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibaciliosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) Aspergillus flavus, Aspergillus fumigatus and Candida albicans.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION

VIRKON S will destroy all viruses, bacteria and fungi which cause diseases including EVA, Herpes 123, strangles, Mud Fever, Skin Lesions, Warts and Ringworm.

DIRECTIONS FOR USE

For Topical Use On Animal; Shampoo infected area with VIRKON S using a clean sponge. Rinse with clean water. Apply three times a day. Repeat as necessary. Stables, Horse Boxes, Feed Rooms, Thoroughly dry clean. Then wash the area manually or with pressure washer with a 1% VIRKON S. Tack, Grooming Equipment, Feeders, Drinkers; Wash by hand using 1% VIRKON S. Rinse with clean water. Blankets and Rugs; Shampoo by hand or spray lightly with a hand sprayer and leave to dry. Shake or vacuum to remove residue. Aerial Spraying to control airborne diseases: By using a knapsack sprayer with fine setting or a VIRKON S SPRAY APPLICATION SYSTEM which automatically sprays the area. Spray for 2-3 minutes twice daily, first thing in the morning and last thing at night.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anemia (Swamp Fever) Adenovirus Pneumonia, Taylorella equigenitalis, Equine Influenza (The Cough) and Rhinitis. Bacterial: Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Strangles and Glanders. Fungi: Dermatophytosis (Ringworm) and Dermatophylosis (Mud Fever).

VIRKON® S

DILUTION CHART

Quantity of		
Final Solution	1% Solution	2% Solution
American		
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125g	60Z	
100g	5oz	
75g	4 oz	
50g	3oz	
	2oz	
	1oz	

Brim full - contains 200g or 7 ounces

The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and Irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England

Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

ACCEPTED with COMMENTS in EPA Letter Dated:

DEC

Under the Federal Insecticide, Fungicide, and Rodenticide Act amended, for the pesticite registered under EPA Reg. No. 62 432



74

62432-1

DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2304 Anhinga Drive Kissimmee, Florida 34743 Ph: 407/344~9803 Fax: 407/344~9980

May 24, 1995

Ms. Ruth G. Douglas (PM32) Antimicrobial Program Branch Registration Division (7505C) U.S. Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460

Attn: Ms. Marianne Clark

Subject: Virkon S (EPA Reg # 62432)

Response To Your Letter of May 5, 1995

Dear Ms. Clark:

In accordance with your letter of May 5, 1995 and our telephone conversation of May 24, 1995, please find enclosed Application for Pesticide Amendment relating to our submission of June 24, 1994. As stated in your letter,

- 1. We have revised the proposed claims, identifying the specific bacteria on our label and
- we have the name of record of this product as Virkon S throughout the text and deleted the Virkon E identification.

Incidentally, Ms. Clark, I am concerned that my current address has not been entered into the EPA computer record since your letter was directed to my previous address. Notification of address change (as indicated above) was formally submitted.

I do wish to thank you for your assistance on this date and the courtesy extended to me. I hope to visit with you and Ms. Douglas on my next visit to Washington and EPA.

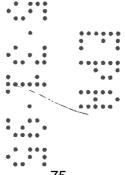
Sincerely,

alan R. Wagner, D. VM. M.S.

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd

ARW/mw

Attachments



Please read Instructions of	n reverse before completing	form.	Form Apr	proved, OMB No. 20	070-0060	Approval expires 11-30-9
(A) SEP	United States Enviro Office of Pesticio Washing Application	de Programs (H ton, DC 20460	tion Agency 7505C)	Registra X Amenda Other	ation	191011
		Section I				
1. Company/Product Number			2. EPA Product Ma	nager	3. Pro	posed Classification
624			Ms. Ruth G	. Douglas	-	None Restricted
4. Company/Product (Name)		PWW		X	The I heat lotted
VIRKON S			# 32			
5. Name and Address of Ap Antec Internat Chilton Indust Sudbury, Suffo ENGLAND Check N this	cional Ltd	NING		is similar or ident		FIFRA Section 3(c)(3) nposition and labeling
		Section I I	F31074			
X Amendment - Explain b	elow		Final printed Agency lette	abels in response to	0	
Resubmission in respon	se to Agency letter dated	5/5/95	"Me Too" App	dication.		
Notification - Explain be	low.		Other - explai	in helow		
record	or this product		gnout text	or Master	Labe	1.
4 44 4 4 4 7 1 7 1 7 1 4 14		ection III				
 Material This Product W Child-Resistant Packaging 	Unit Packaging	Water S	Soluble Packaging	2. Type of 0	Container	
Yes*	Yes	П			Metal	
				X	Plastic	
No No	X No If "Yes," No. 6	er II "Yes,"			Glass Paper	
* Certification must be submitted.	If "Yes," No. p Unit Package wgt. conta			ainer	Other (Spe	ecify)
3. Location of Net Contents		s) of Retail Con		5. Location of Lai	bel Directio	ns
	ontainer	mama E	Kg, 2.5 K	On Labelia	ng accomp	anying product
6. Manner In Which Label Is		Lithograph Paper glued Stenciled	X Othe	Pressure	Sens	itive)
4. Contest Brist 10	Marine allegate had a delicate	Section IV	shiples he are true.	d	agen this	naslinas i
Contact Point (Complete Name	items directly below for identif	Title	JUBI TO DE CONTACTED,			Repolication.) No. (Include Area Code)
Alan R. Wagner	, D.V.M., M.S.	Manage	er, Regulator for Antec	tory Affai	rs 40	7/344-9803
	Certific is I have made on this form an nowingly false or misleading s	cation d all attachmen	ts thereto are true, a	ccurate and comple	te.	Date Application Received (Stamped)
2. Signature		3. Title	or Pocula	tom: 255-1		
alan R Wag	rir, D.V.M., M.S.		er, Regula for Antec	100		Ltd.
4. Typed Name Alan R. Wagner		5. Date May	24, 1995			• • • • •
PA Form 8570-1 (Rev. 12-	00) Previous editions are			A File Copy (origin	al)	76 Yellow - Applicant copy

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 N Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling; 5. Three copies of any data submitted: 6. Authorization latter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Planse read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, 111, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

 $\underline{\mathsf{SECTION}\ \mathbf{I}}$ - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific FPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by ... "; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in top nection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types.

Indicate the size of the individual packets and number per retail container.

Type of Retail Container - Indicate type of container in which product will be marketed.

Location of Net Contents - Specify the net contents of all retail containers for your product.

5. \$22(s) of Refail Container - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Heaver in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV. (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.
6. EPA Use Dnly.

Reviewer ID Submission No. Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 69432-1 PM 32 Action Code 300 10 Descriptor (Amend/Resultations only) Submission of Updated Labels [](C) Certification |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant Packaging / (N) No //(S) Service Person [20] Registration Type: / (R) Non-residential Use Only (1) Conditional (2) Unconditional / (N) Not-Applicable 25 Proposed Classification: 30 Final Classification: // (R) Restricted // (R) Restricted (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: |40 | Date Received by PM 1017211914 1016 214 914 017 011 9H |80 | Method of Support: // (6) Owner Submission . / (1) Cite-All [(4) Not Applicable [(7) Total Submission (5) Not Submitted (8) Selective Method RESPONSE RESPONSE DATE DUE DATE Reviewers Requested: SENT RETURNED DATE CH EF PL DEB NDEB TB EEB **EFGB** 115 FINAL FINAL Response 2 120 Response / /(N) No 75-DAY RESPONSE DUE DATE: / /(Y) Yes

MAY 05 1995

Dr. Alan R. Wagner, D.V.M., M.S. Agent for Antec International Limited Chilton Industrial Estate Sudbury Suffolk C010 6XD England

Dear Dr. Wagner:

Virkon S Subject:

EPA Registration No. 62432-1

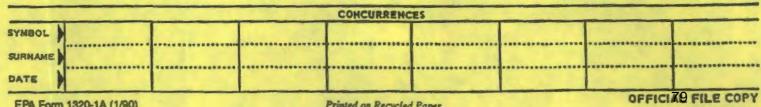
Your Amendment Dated June 24, 1994

This is in response to your amendment of revised labeling with additional uses for the subject product. The following comments apply.

Labeling:

The proposed labeling is unacceptable for the following reasons:

- The proposed claims such as 'clostridium spp., Leptospira spp, Camplylobacter ssp" are unacceptable, the specific bacteria must be mentioned.
- The name of record for this product is "Virkon S." 2. Throughout the label text wherever reference is made to a product name, instead of referring to Virkon S or Virkon E, indicate "this product". Only composite/master labeling (with all the uses) bearing the basic product name should be submitted for review. We do not review or stamp additional brand name labeling, such as a label with the name "Virkon E" or any other name other than "Virkon S."

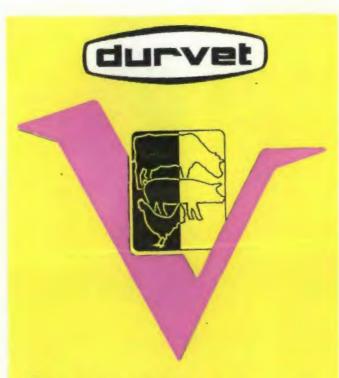


If you have any questions about these comments, please call Marianne Clark at (703) 305-7879.

Sincerely yours,



Ruth Douglas Product Manager (32) Antimicrobial Program Branch Registration Division (7505C)



BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pylondis Idebsielle pneumoniae Escherichla coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphylococcus aureus Mycoplasma gallisepticum Clostricium app	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotrachellis Avian Influenca Marek's Disease Egg Drop Syndrome	Aspergillus llanus Candida albicans

ACTIVE INGREDIENTS

Potassi	um peroxymonosullate	*** ** 6	U.4	7
	Chloride		1.5	%
INERT	INGREDIENTS		1 8	%
TOTAL		10	חח	PL.

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10bs Net Weight: Distributed By:

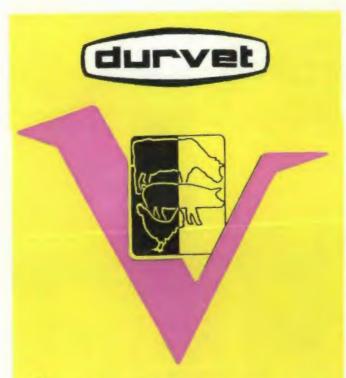
....



301 Baybrook Street Thomasville, GA 31792

VIRISIN See amogistered trademark of and manufactured by Antec attendational Limited U.S. Patent No. 4822512

Made in England by Anler Joernational Limited



Virkon_®S Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA-	VIRUSES OF	FUNGI
Streptococcus pyogenes Staphylococcus aureus Klebsiella pneumonae Escherichia coli Salmonella typhimunium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus epidermidis Mycoplastiva sop Bordetella bronchiseptica Pasteurella multocida Campylobatter spp Erysipelothrik muslopathae	Hog cholera Swine influenza TGE Blue eye Porcine parvovirus Rotaviral diarrhoea Vesicular stornatitis Pseudorabies	Aspergillus flavus Candida albicans
Leplospira spp Clostridium spp Actinobacillus pleuropneumoniae Treponema hyodysenteriae		

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792 Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram negative bacteria, fungl (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION

VIRKONS is recommended for use in hatchenes, in chicken houses, and in processing plants.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchilis, Infectious Bursal Disease, Laryngolrachetis Avian Influenza, Marek's Disease and Egg Drop Syndrome. Fungi; Aspergiffus flavus and Candida ablicans. Bacteria; Streptococcus pyogenes, Campylobacter pyloridis, Infectious Bronchilis, Nebssella pneumoniae, Escherichia cofi, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum, Necrotic entertis.

HATCHERIES: VIRIKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling tans, chicken houses, transfer trucks. trays, and plastic chick boxes (use 2% solution for Mycoplasma and Aspergillus Ravus).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either proceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic wet loggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed and water throughs, remove manure and litter and spray floors and side walls with YIRIKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRIKON 5 (use 2% solution for Mycoplasma and Aspergifius llavus). After contact for ten minutes, rinse with potable water Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Viruses of Blue Eye, Hog Cholera, Porcine Parvo Disease Vesicular Stomafilis, Pseudorabies, Rotavral Diarrhosa, Swine Influenza, Foot and Mouth Disease and TGE. Bacteria of Arthrills, Meningitis, Athrofic Rhinitis, Pasteurellosis, Colibacillosis, Enteritis, Erisipelas, Leptospirosis, Mastitis, Necrobo Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) Aspergillus flavus and Candida albicans.

VIRKON is recommended for use in Farrowing pens, weaner accomodat grower accomodation and finisher accomodation and processing plants. VIFIKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and Aspergillus flavus).

VIRICON S is recommended for use in logging (wet misting) operations or as an adjunct either proceeding or following regular cleaning and disinfecting procedures. VIRICON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been

PROCESSING PLANTS: For disinfecting and cleaning walls, cuilings, and

STORAGE & DISPOSAL: Store in a cool dry place in lightly closed container Always replace lid after use. Wash emply container thoroughly and dispose of in trash.

Virkon, S

Quantity of Final Solution	1% Solution	2% Solution
American 1 gallon 10 gallons 50 gallons	1.3 ounces 13.4 ounces 66.8 ounces	2.7 ounces 26.7 ounces 133.5 ounces



For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive, Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water Get medical attention if Irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.



Manufactured for

Durvet Inc. Blue Springs, Missouri, 84013-1-800-821-5570
EPA Reg. No. 62432-1-12281. EPA Est No. 62432-604-004
Made in England by Antec International Limited



Virkon S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals viruses Gram positive and Gram negative beclefts, lungi (molds and yeasis), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling. This powder formula is easily diluted for use in manual or machine operations.

POINTRY PRODUCTION

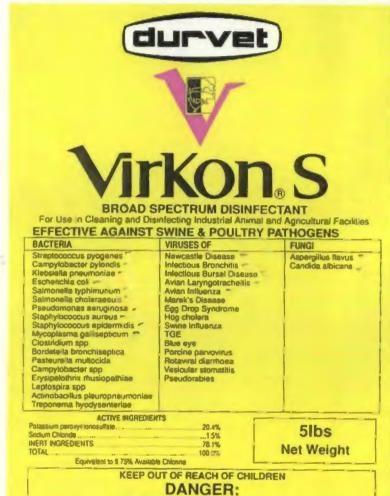
VIRKON S is recommended for use in hatcheries, in chicken houses, and in processing plants.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotrachellis Avian In Jenza Marek's Disease and Egg Drop Syndrome Fungi Aspergillus Ilavus and Candida albicans, Bacteria; Streptococcus pyogenes, Campylobacter pyloridis Infertinus Reportitis, Klaheiella preumonize Escherichia col. Salmonella lyphimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus, Staphylococcus epidermidis,-Mycopiesma galisepticum Necrotic enternis

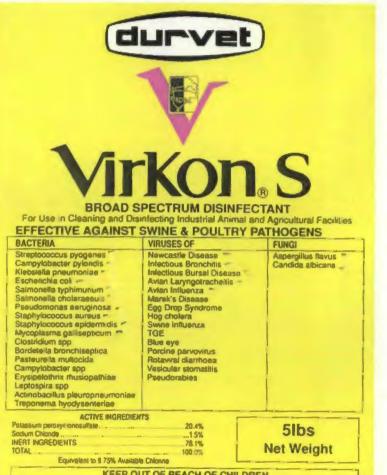
HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters evaporative coolers, humidilying systems, ceiling lans, ptastic chick boxes fuse 2% solution for Mycoplasma and Aspergillus flavus)

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures VIRKON S at 1-29, solution is suitable. Fog (well mist) until the area is moist using manufacturer's use directions

Continued on reverse side.







Virkon, S

Quantity of Final Solution American	1% Solution	2% Substan
1 gallon	1.3 curces	2.7 custoes
10 gallons	13.4 curces	26.7 custoes
50 gallons	66.8 curces	133.5 custoes



For DISINFECTING use a rate of 7.5 gallons/1000 eq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallone/100 sq. fl. PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before rouse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if imitation

IF INHALED: or symptoms of coughing, chaking, or wheezing are troublesome, remove to tresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.



301 Baytorook Street, Thomasville, QA 31792



Durvet Inc. Blue Springs, Missouri, 64015-1-800-821 5570 EPA Reg. No. 62432-1-12281 EPA Est. No. 62432-EN-001 Virkon is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512 Made in England by Antec International Limited

DIRECTIONS FOR USE CONTINUED

BROILER/BREEDER HOUSES:

Following removal of chickens, feed and water troughs, remove manure and litter and spray floors and side walls with VIFIKON S at 1% Thoroughly wash waterers and leaders with a 1% solution of VIRKON S (use 2% flavors). After contact for ten strender, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dred.

SWINE PRODUCTION

CONTROLS: Viruses of Blue Eye, Hop Cholera Percine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Rotaviral Distringe, Swine Influenza, Foot and Mouth Disease and TGE Becteria of Arthritis, Meninghs, Athrofic Athintis, Pasteurollosis, Colibacidosis, Enteritis, Erisipolas Pleuropneumonia, Salmonellosis and Swine Dysentery, Fungi (molds and yeasts) Appergitus flavus and Condida albecans.

VIRKON is recommended for use in Farrowing pans, weaver accommodation grower accommodation and hnisher accompdation and processing plants. VIAKON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and Aspergillus

VIRKON S is recommended for use in logging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures VIRKON'S at 1-2% solution is suitable Fog (wet mist) until the area is moist using manufacturer's use directions.

FOR AIR SAMITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been togged.

STORAGE & DISPOSAL: Store in a cool, dry place in tightly closed container. Always replace lid after use, Wash empty container thoroughly and dispose of in trash





PROJ DATE:

DP BARCODE: D206282

SUBMISSION: S470454

DATA PACKAGE RECORD

BEAN SHEET

DATE: 08/08/94 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 300 ADMN-LBL REV AMND NO DATA

RANKING : 5 POINTS ()

CHEMICALS: 063604 Potassium peroxymonosulfate

013905 Sodium chloride

20.4000%

01.5000%

ID#: 062432-00001 VIRKON S

COMPANY: 062432 ANTEC INTERNATIONAL LTD

PRODUCT MANAGER: 32 RUTH DOUGLAS
PM TEAM REVIEWER: BARBARA PRINGLE MC 4703-305-7964 ROOM: CM2 280

RECEIVED DATE: 07/01/94 DUE OUT DATE: 09/29/94

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 206282 EXPEDITE: N DATE SENT: 08/08/94 DATE RET.: / /

EMICAL: 063604 Potassium peroxymonosulfate

DP TYPE: 001 Submission Related Data Package

CSF: N LABEL: Y

ADMIN DUE DATE: 09/22/94 DATE OUT ASSIGNED TO DATE IN NEGOT DATE: / /

11 / / DIV : RD BRAN: AB 11 SECT: EETMS REVR :

CONTR:

ejoche Jatura

* * * DATA REVIEW INSTRUCTIONS * * *

Review revised label with additional uses

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * *

BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL DP BC

M. Nieues 8/10

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

m. 128-8-94 00	1 8-17-94
Reviewed by Michael Nieves	Date 8-17-94
EPA Reg. No. or File Symbol	62432-1
EPA Petition or BUP No.	None
Date Division Received_	
Type Product <u>Disinfectan</u>	t (Animal & Agriculture)
MRID No(s)	None
Product Manager	R. Douglas (PM 31)
Product Name	Virkon S
Company Name	Antec International LTD
Submission Purpose The submission additional us	
Type Formulation	Powder
Active Ingredients(s)	<u> </u>
Potassium peroxymonosulfate	

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol	62432-1
EPA Petition or EUP No	None
Date Division Received	7-1-94
Type Product Disinfec	tant (Animal & Agriculture)
MRID No(s)	None
Product Manager	R. Douglas (PM 31)
Product Name	Virkon S
Company Name	Antec International LTD

200.0	Introduction:
200.1	Uses:
	See attached proposed label dated 7-1-94.
200.2	Background Information:
	The submission is an application to add additional uses.
200.3	Factors Affecting Amount/Type of Data Required:
	None
201.0	Data Summary
	None
201.1	Abstract of Test Reports:
	None
201.2	Brief Description of Tests:
	None
201.3	Data Summaries
	None
201.4	Other Summarized Results:
	See Recommendations under 202.0.

- 202.0 Recommendations
- 202.1 Efficacy Supported By The Data:

No efficacy data were submitted for this amendment.

203.0 Labeling:

The proposed labeling is unacceptable for the following reasons:

1. The registrant is proposing disinfecting claims against certain microorganisms that are equine and swine pathogens. Some of the new microorganisms mentioned in the proposed labeling are also pathogens against humans, therefore the registrant must submit efficacy data demonstrating that the product is efficacious against those specific pathogens that are pathogenic to humans. Specifically data should be submitted for the following microorganisms:

BACTERIA:

Streptococcus pyogenes
Camplylobacter plyoridas
Klebiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis

VIRUSES:

Newscastle Disease Infectious Bronchitis Infectious Bursal Disease

FUNGI:

Candida albicans

- All of these (item)
 claims were on
 the last accepted
 label. Therefore, no
 data are required
 at this time. Well
 have to request it
 at reregistrations
- 2. The "blue bean sheet" package contained labeling prints for the product: VIRKON E (EPA Reg. No. 624321-12281); the proposed labeling language for the product VIRKON S includes some language that mentions the product VIRKON E. Please see the last page of the proposed labeling for VIRKON S.
- 3. Proposed claims such as "Clostridium spp, Leptospira spp, Camplylobacter ssp" are unacceptable, the specific bacteria must be mentioned.



United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

Registration x Amendment OPP Identifier Number 101010

ALLIA	Applic	ation for Pe	sticide:	Other	191019
		Section I			
1. Company/Product Number 62432 4. Company/Product (Name Virkon S			2. EPA Product Mana Ms. Ruth G PM# 32	. Douglas -	Proposed Classification None Restricted
5. Name and Address of Ap Antec Interna Chilton Indus Sudbury, Suff ENGLAND Check if this	tional Ltd trial Estate				ith FIFRA Section 3(c)(3) composition and labeling
		Section II			
Amendment - Explain by Resubmission in responsibilities Notification - Explain be	nse to Agency letter date		Final printed lat Agency letter of "Me Too" Applied	cation.	
Explanation: Use addition Submission of Final printed Identification revised on Ma	Master EPA I labels (5 ea n of Antec In	Label upda ach) for s	te for swine	uine species	•
Tevised on Ma	SLEE EPA Labe	Section III			
T. Material This Product W	fill Re Packaged In:	Section in			
Child-Resistant Packaging Yes* No Certification must be submitted.		No. per If "Yes	Soluble Packaging Yes No No No. pe ge wgt. contain	I CITIES	3
3. Location of Net Contents				5. Location of Label Din On Label On Labeling according	ections ompanying product
6. Manner In Which Label Is	Affixed To Product	Lithograph Paper glued Stenciled Section IV	Other	(Pressure Se	
1. Contact Point (Complete	items directly below for it			necessary, to process	this application.)
Name Alan R. Wagne		Title Manag	er, Regulate	Teleph	one No. (finclude Area Code) 305/553-9017
l certify that the statement i acknowledge that any k both under applicable law	ts I have made on this for nowingly false or mislead	rtification m and all attachme ling statement may	nts thereto are true, acc be punishable by fine	curate and complete.	6. Date Application Received (Stamped)
2. Signature Olan R. W.	agnow D.V.M.	3. Title Manag Agent	er, Regulate for Antec		l Ltd
4. Typed Name Alan R. Wagne		5. Date	24, 1994		88

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERNORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

2. Confidential Statement of Formula (EPA Form 8570-4); 3. Formuletor's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling; 5. Three copies of any data submitted: 6. Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller then 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections 1, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections 1, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency Letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION Iff (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.
3. Location of No. Contents - Specify the net contents of all retail containers for your product.

4. Size(s) of Retail Containers - Specify the net contents of all retail containers for your product.
5. Location of Use Directions - Indicate the location of the use directions for your product.
6. Hanner in which tabel is affixed to product - Indicate the method product tabel is attached to retail container.

SECTION IV. (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Only.



301 Baybrook Street, Thomasville, Ga. 31792

January 4, 1994

Susan T. Lewis Branch Chief Room 229, E.P.A. Office of Pesticide Programs 1921 Jefferson Davis Drive Arlington, VA 22202

Dear Ms. Lewis:

Effective January 1, 1994 a new regulatory agent will represent Antec Internationnal Ltd., at E.P.A. Antec International manufactures Virkon S, E.P.A. Reg. No. 62431-1.

The name of the agent is Dr. Alan R. Wagner. His title and address follow:

> Alan R. Wagner, D.V.M., M.S. Manager, Regulatory Affairs 4302 S.W. 147th Place Miami, FL 33185 Phone 305/553-9017

Please communicate with Dr. Wagner on all E.P.A. matters concerning Virkon S and Antec International, Ltd.

Sincerely,

H.J. Van Veen

President

MICROTEC, INC.

U.S. Agents for Antec International, Ltd.

cc: R. Auchincloss, Antec International, Ltd.

Dr. Alan R. Wagner







DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

Private Counsultation

4302 S.W. 147th Place Miami, Florida 33185 (305) 553-9017

June 24, 1994

Ms. Ruth G. Douglas (PM32)
Antimicrobial Program Branch
Registration Division (7505C)
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, D.C. 20460

Subject: Virkon S (EPA Reg. # 62432)

Dear Ms. Douglas:

Sincerely,

Attachments

Please find "Application For Pesticide Amendment" updating our EPA Approved Master Label that you discussed with me during our recent meeting in Washington, D.C. on June 14, 1994. We have included on the Master EPA Approved Label that you presented to me, the swine and equine specie claim accompanied by printed labels (5 each) identifying efficacy claims for microbial organisms as listed.

Also, in conformance with our discussions, we have identified ANTEC INTERNATIONAL LTD, Windham Road, Chilton Industrial Estates, Sudbury Suffolk C010 6XD, England as the basic registrant identified on the Master EPA Approved Label. This submission does not modify label requirements for DIRECTIONS FOR USE; PRECAUTIONARY STATEMENTS; OR STORAGE AND DISPOSAL as approved on the Master EPA Label.

I certainly appreciated the opportunity to meet with you, Ms. Douglas, in my role as Country Agent USA for Antec International Ltd and to review label submissions and other pertinent Antec data that has been submitted to your office.

We will be anxious for your review and approval of the label submissions as we discussed, Ms. Douglas, so the labels can be released for the product package. If you should have any questions regarding the submission please call me at 305/553-9017. Enclosed, as per your request, is a copy of the letter appointing me as regulatory agent for Antec International Ltd.

Again, thank you for your excellent assistance and the courtesy extended to me and I shall be looking forward to our next meeting.

Alan R. Wagner, D.V.M., M.S.
Manager, Regulatory Affairs
Agent for Antec International Ltd.

ARW/mw

62432-1

AKENDKENT

		Expet 1	91019
WITH DATA	Init. Date	NO DATA	Init. Date
PEU		. PEU	2.w. 2-8-94
SIG (DATA)		PH	
FEU			
PM			
	REGULAR APPLICATION FOR AN	ENDKENT	
WITH DATA	Init. Date	NO DATA	Init. Date
FEU		FEU	
SIG (DATA)		PH	
PM			
	PEU SIG (DATA) PEU PM WITH DATA FEU SIG (DATA)	WITH DATA Init. Date PEU SIG (DATA) PH REGULAR APPLICATION FOR AN WITH DATA Init. Date FEU SIG (DATA)	PAST TRACE * APPLICATION FOR AMENDMENT HITH DATA Init. Date PEU SIG (DATA) PH REGULAR APPLICATION FOR AMENDMENT WITH DATA Init. Date FEU SIG (DATA) PH PH PH PH PH PH PH PH PH P

• Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

07/11/94

ALAN WAGNER, D.V.M., M.S. DR ALAN WAGNER, DVM, MS 4302 SW 147 PLACE MIAMI FL 33185

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S

COMPANY NAME: ANTEC INTERNATIONAL LTD.

OPP IDENTIFICATION NUMBER: 191019 EPA REGISTRATION NUMBER: 62432-1

EPA RECEIPT DATE: 07/01/94

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

Front End Processing Staff Information Services Branch

Program Management and Support Division

DEMESME Reviewer ID Submission No. 5483257 Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENIMENTS File Symbol/Reg. No. 62432-1 PM 32 Action Code 300 10 Descriptor (Amend/Resulmisions only) Final label 5 Intrastate Call-in / / (Y) Yes 15 Child-resistant /_/(C) Certification Packaging (N) No /(S) Service Person |20| Registration Type: / (R) Non-residential Use Only (1) Conditional (2) Unconditional / (N) Not-Applicable 25 Proposed Classification: 30 Final Classification: // (R) Restricted // (R) Restricted // (G) General // (N) Not Classified 35 Date on Application: 04 EPA Received Date: 01221915 012218915 113019915 80 Method of Support: (1) Cite-All // (6) Owner Submission (4) Not Applicable (7) Total Submission [(5) Not Submitted [(8) Selective Method DATE DUE DATE RESPONSE RESPONSE Reviewers Requested: SENT DATE RETURNED CODE DATE CH EF PL DEB NDEB TB EEB EFGB 115 FINAL Response 120 Response ACTION Code 3 7 75-DAY RESPONSE DUE DATE: //(Y) Yes / /(N) No

Bern

DR. ALAN R. WAGNER

Regulatory Affairs and Technical Services

Private Consultant Clinical Investigations

2304 Anhinga Drive Kissimmee, Florida 34743 Ph: 407/344~9803 Fax: 407/344~9980

February 21, 1995

Ms. Ruth G. Douglas (PM32) Antimicrobial Program Branch Registration Division (7505C) U.S. Environmental Protection Agency 401 M Street S.W. Washington, D.C. 20460

Subject: VirKon S and VitKon E (EPA Reg. # 62432-1) Submittance of Final Printed Lalbels

Dear Ms. Douglas:

In accordance with your letter of December 1, 1994, please find enclosed final printed labels (5) for products identified as VirKon S and VirKon E.

Thank you Ms. Douglas for your prompt review of our application and informing us of the acceptability of the submission. I also appreciate the assistance and courtesy extended to me and I shall be looking forward to our next meeting in Washington, D.C.

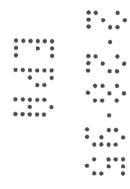
Sincerely,

Alan R. Wagner, D. V.M., M.S.

Agent for Antec International Ltd.

ARW/mw

Enclosures



Please read Instructions	on reverse before co	ompieting form.	Form A	pproved. (OMB No. 207	0 0060.	Approval expires 11-30-93
(A) SEP	Office	tes Environmental Prot of Pesticide Programs Washington, DC 2040 plication for Po	(H7505Č) 50 esticide:		legistrat Imendm Other		OPP Identifier Number
		Section					
1. Company/Product Number	r		2. EPA Product M	lanager		3. Pro	oposed Classification
62432-1			Ms Ruth G	. Dou	glas		None Restricted
4. Company/Product (Name	»)		PM#			لعا	Hestricled
VIRKON S		24.21	32				
5. Name and Address of Ap	plicant (Include ZIP (Code)					FIFRA Section 3(c)(3)
Antec Internation Industry, Su	ustrial Est ffolk C010	tate	to:		er or identic	al in co	mposition and labeling
Check if this	is a new address		Product Name_				
		Section I					
Amendment Explain b	rolaw.		Final printer	d labels in	response to		
			Agency lett	ter dated_	Decem	oer	1, 1995
Resubmission in respon	nse to Agency letter	dated	"Me Too" A	polication.			
Notification - Explain be	olow.		H				
			Other - expl	IBIN DEIOW.			
. VIRKON S . VIRKON E							
		Section III					
1. Material This Product V	/III Be Packaged In:						
Child-Resistant Packaging	Unit Packaging	Wate	Soluble Packaging	2	. Type of Co	ntainer	
Yes*	Yes		Yes			letal lastic	
X No	X No	X	No		A_	lass	
	If "Yes,"	No. per If "Ye		. per		aper ther (Sp	noih.)
Certification must be submitted.	Unit Package wgt.			ntainer			
3. Location of Net Contents	Information	4. Size(s) of Retail C			On Label	l Direction	ons
X Label C	ontainer	2.5 Kg., 5.				accomp	panying product
6. Manner In Which Label Is	Affixed To Product	Lithograph Paper glued	Y Ot	her (pro	SCHEO!	Cone	itive_)
		Stenciled					
		Section IV					
1. Contact Point (Complete	items directly below	for identification of indi	vidual to be contacte	ed, if neces			
Name			ent for An	tec	10	epnone	No. Tinclude Area Code)
Alan R. Wagi	ner, D.V.M.	., M.S. In	ternationa			***	•
I certify that the statement I acknowledge that any k both under applicable law	nowingly lalse or mis	Certification s form and all attachme sleading statement may	ents thereto are true, be punishable by fi	accurate a	and complete isonment are		6. Date Application Received (Slambed)
2. Signature	agner D. V.M.	M.S. 3. Title	gent for A	ntec			• • • • • • • • • • • • • • • • • • • •
Alan R. Wagi	ner, D.V.M.		nternation		d.		
4. Typed Name		5. Date					
Alan R. Wagi	ner, D.V.M.	, M.S. F	ebruary 21	, 199	5		00
							96

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

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2. Confidential Statement of Formula (EPA Form 8570-4); 3. Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling; 5. Three copies of any data submitted:

6. Authorization letter where applicable;

7. Matrices where applicable. Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

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- SECTION I This section must be completed, as applicable, for all registration actions.

 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Humber.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in ell registration matters. The name and complete mailing

address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered

product. This section is not to be used for a new application for registration.
1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION TIB (Packaging and Container Information) - This Section must be completed for all applications

- submitted in connection with men registration or applicable amendments.

 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
- Indicate the size of the individual packets and number per retail container.

 2. Type of Retail Container Indicate type of container in which product will be marketed.

 3. Location of the Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product. 5. Location of Use Directions - Indicate the Location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.
1-5. Self-explanatory.

6. EPA Use Only.

Virkon.S

1 1 1 1 1

BROAD SPECTRUM DISINFECTANT VIRKON S is effective against numerous microorganisms affecting animals: viruses, Gram positive and Gram regative bectaria. fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.
This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE

VIRKON S is recommended for use in hatcheries, in chicken houses, and in Flatile graduction.

CONTROLS: Viruses of Nawcastle CONTROLS: Virtues o reviewe and property of the property of th Bacteria; Streptococcus pyogenes, Campylobacter pyloridis, lafectious Bronchitts, Klabalella pneumonise, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonae seruginosa, Staphylococcus aureus, Staphylococcus spidernidis, Mycoplasma nallisanticum. Nacrolic enteritis.

HATCHERIES: VIRKON 5 at 1% solution is generally suitable for cleaning and disintecting batchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycopiasma and Aspergillus florus and 3% solution for Aspergillus fumigatus).

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. For (wet mist) until the area is moist using automatic wet toggers according to

manufacturer's use directions.
VIRIXON S passes the AOAC germicidal and detergent sanitiser test at a concentration of 0.5% (1:200) in the presence of 200 ppm

Continued on reverse side



NOT REVIEWED In Accordance with PR Notice 82-2-1 Based on Druft Labeling Dated



Virkon.S

DILUTION CHART		
Quantity of Final Solution American	1% Solution	2% Solutio
1 gallon 10 gallons 50 gatlons	1.3 gunces 13.4 gunces 66.8 gunces	2.7 ounces 26.7 ounces 133.5 ounce





tevel 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.

For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. M. PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation

IF INHALED: or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Distributed by



301 Baybrook Street, Thomasville, GA 31792

Manufactured for







Durvet Inc. Blue Springs, Missouri, 64015-1 800-821-5570 EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001

Virkon is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512 Made in England by Antec International Limited

DIRECTIONS FOR USE CONTINUED

BROILER/BREEDER HOUSES:

Pollowing removal of chickens, feed and water troughs, remove manure and litter and appry floors and side walls with VIRIXON S at 1%, Thoroughly wash waterers and leeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and Aspergiflus flavus and 3% solution for Apergillus fumigatus). After contact for ten minutes, rinse with potable water. Do not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Vauses of Hog Cholers. Porcine Parvo Disease, Vesicular Storradiis, PRRS, Pseudorabies, Rotaviral Diarrhea, Swins Influenza, Foot and Mouth Disease and TGE, Bacteria of Arthritis, Meningilla. Atrophic Rhinkis, Pasteurellosis Collibecillosis, Enteritis, Erysipelas, Leptospirosia, Mastitis, Necrotic Enteritis. Pleuropneumonia, Salmonoliosis and Swine Dysentery: Fungi (molds and yeasis) Aspergillus fluvus, Aspergillus fumigatus and Candida abicana.

VIRKON S is recommended for use in Farrowing pens, weaper accomodation grower accomodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally sutable to cleaning and dishlecting (use 2% solution for Mycoplasma and Aspergillus flavus and 3% solution for Aspergillus

VIRKON S is recommended for use in logging (wet misling) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to many darb mar's use directions.

FOR AIR SANITIZING: Use VIRKON \$ at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been logged.

STORAGE & DISPOSAL: Store in a cool. dry place in tightly closed container. Keep out of reach of children. Always reptace lid after use. Wash emply container thoroughly and dispose of in trash.



NOT REVIEWED In Accordance with PR Notice 82-2 Based on Draft Labeling Dated



PRECAUTIONARY STATEMENTS
INTERESTO BEARING AND DEMONSTIC ANNALLS
DANGER
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CONTROLS.

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May Service Statement Statemen



NET CONTENTS 1.3 02 MAKES ONE GALLON. DISINCENTRACE

> 78.1% 100.0%

BROAD SPECTRUM EQUINE DISINFECTANT/DETERGENT/WASH

FOR CLEANING AND DISINFECTING NEABLES, EQUIPMENT AND ARRIAL DISINFECTION

ACTIVICINGUEDITYTE Pelessions perseymmentulines fourthum chronish.

KIND OUT OF BEACH OF CHILDREN DANGER

PRINCIPAL IN MICROTEC ANIMAL NUTRITION, INC. 161 Impleyed Arest, Thomseriffe, GA 11792 Phone (912) 225-1182

Virkon.S

DRIGATO OFFICE THAT DESIGNED A CLASSIFIE TO THE ACT OF THE ACT OF



company number.

SEPA.

USEN

ONMENTAL PROTECTION AGENCY F PESTICIDE PROGRAMS (TS - 767) WASHINGTON, DC 20460

NOTICE OF SUPPLEMENTAL REGISTRATION OF DISTRIBUTOR

(Please read instructions before completing)

EPA REGISTRATION NO. OF PRODUCT

DISTRIBUTOR COMPANY NUMBER

1-778-91-9 6016-06120

63690/2016

NAME AND ADDRESS OF BASIC REGISTRANT (print or type, include ZIP code)

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609

'AME OF REGISTERED PRODUCT (basic product name accepted by EPA)

VIRKON-S

DISTRIBUTOR PRODUCT NAME

VIRKON-S

NAME AND ADDRESS OF DISTRIBUTOR (print or type; include ZIP code)

AGRI-BIO CORPORATION 966 DORSEY ST., GAINESVILLE, GEORGIA 30501

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationary, to the Registration Divi-

INSTRUCTIONS

After a registrent has obtained final registration for the basic product, the

registrent may then supplementally

register and distribute his/her product. One form must be submitted for each distributor brand and must

be signed by the distributor involved.

The form must state the basic registration number and the distributor

stationary, to the Hegistration Division to have a number assigned prior to submitting a Distributor Notification to the Agency.

Notification forms must be submitted by the basic registrant. They must have the concurrence and signature of both the registrant and the distributor.

When submitting several forms for the same basic product, submitting them together will facilitate processing.

NOTE: DO NOT submit distributor product labels.

CONDITIONS

- The distributor product must have the same composition as the basic registered product.
- The distributor brand product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so no other changes are necessary.
- The product must remain in the manufacturer's unbroken container.
- The label must bear the EPA registration number of the basic registered product, followed by a hyphen and the distributor's company number.
- 6. Distributor products must bear the name and address of the distributor qualified by such terms as "packed for . .," "distributed by . . ,"; or "sold by . .," to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor brand products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic groduct.

DISTRIBUTOR

We intend to market under the Distributor Product Name and Number specified above, subject to the conditions specified on this form.

SIGNATURE AND TITLE DEDISTRIBUTOR

DATE 6 MAR 90

D.VIS

RECEIVED BY FPA REGISTRATION D.V.S.ON ON THE DATE STAMPED BELOW

3200

DOME

REGISTRANT

It is requested that the Registration Record of this jacket include the Distributor Product specified above, subject to the conditions specified on this form,

SIGNATURE AND TITLE OF REGISTRANT

mall L. Gilbert, Ductor Feel Holdstein R.F.D.

March 7,90

3 - 31-90

EPA Form 8570-5 (Rev. 4-83) Previous editions are obsolete.

APPLICANT - Send only original to EPA - Retain copies

Submission No. Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 62432-/PM 32 Action Code 30/ |10| Descriptor (Amend/Resubmissions only) Attach to 6/24/94 Amend ment-Packaging / / (N) No / /(S) Service Person |20| Registration Type: / (R) Non-residential Use Only (1) Conditional (2) Unconditional / (N) Not-Applicable |25| Proposed Classification: |30| Final Classification: (R) Restricted (R) Restricted (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: 40 Date Received by PM 018 219 914 019 016 914 5019 113 914 MD DAY YR MO DAY YR MO DAY YR |80 | Method of Support: (1) Cite-All (6) Owner Submission. (4) Not Applicable (7) Total Submission / / (5) Not Submitted / / (8) Selective Method RESPONSE RESPONSE DATE DUE DATE Reviewers Requested: SENT DATE RETURNED CODE DATE CH EF PL DEB NDEB TB EEB **EFGB** 115 FINAL Response 1120 | Response ACTION Code 101 75-DAY RESPONSE DUE DATE: / /(Y) Yes / /(N) No

Reviewer ID

DEC 0 1 1994

Alan R. Wagner, D.V.M., M.S. Agent for Antec International Ltd. Regulatory Affairs and Technical Services 4302 S.W. 147th Place Miami. FL 33185

SUBJECT: VIRKON S

EPA Registration No. 62432-1 Amendment DAted August 29, 1994

Dear Dr. Wagner:

This is in response to your amendment dated August 29, 1994 requesting to add Porcine Reproductive and Respiratory Syndrome (PRRS) viruses and the fungus Aspergillus fumigatus claims to your label. The amendment is acceptable and no further data is required since these claims are not related to human health.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. Submit five copies of the finished label before you release the product for shipment bearing the amended labeling.

If you have any further questions, please contact Ms. Barbara Pringle at (703)305-6484.

Sincerely,

Ruth G. Douglas Product Manager 32 Antimicrobial Program Branch Registration Division(7505C)

CONCURRENCES JOSMYS SURNAME DATE OFFICIAL FILE COPY

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

*U.S. GPO: 1994-522-503/82085

EOUINE BACTERIA

Clostridial diarrhea

Salmonellosis

Enteric Colibacillosis

Fistulous Withers (Poll Evil)

Contagious Equine Metritis (CEM)

Strangles, Glanders

EQUINE VIRUSES

African Horse Sickness

Equine Viral Arteritis (Pink Eye)

Coital Exanthema

Myeloencephalopathy

Rhinopneumonitis

Equine Contagious Abortion

Equine Papillomatosis

Equine Infectious Anemia (Swamp Fever)

Adenovirus Pneumonia

Equine Influenza (The Cough)

Rhinitis

EQUINE FUNGUS

Dermatophytosis (Ringworm)

ermatophylosis (Mud Fever)

Antec International

(Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes Campylobacter plyoridas Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus aureus Staphyloccoccus epidermidis Mycoplasma gallisepticum Clostridium spp

VIRUSES OF

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease

Avian Laryngotracheitla Avian Influenza

Marek's Disease Egg Drop Syndrome

FUNGI

Aspergillus flavus Aspergillus fumigatus

SWINE BACTERIA

hyodysenteriae.

Bacteria: Bordetella bronchiseptica, Pasteurella multocida, Campyiobacte:

app, Erysipelothrix rhusiopathiae,

SWINE VIRUSES: Hog cholera,

Vesicular stomatitis, Pseudorabies,

Swine influenza, TGE, Porcine

parvovirus, Rotaviral diarrhea.

Respiratory Syndrome (PRRS).

Porcine Reproductive and

Leptospira spp, Actinobacillus

pleuropneumoniae, Treponema

Candida albicans

ACCEPTED with COMMENTS in EPA Letter Dated

Under the Festeral Insecticids. Fungicide, and Resentingle Act as amended, for the posttrole interest under KPA Nov. No.

Equivalent to 9.75% Available Chlorine

. 1.5%

.100.0%

KEEP OUT OF REACH OF CHILDREN DANGER:

ACTIVE INGREDIENTS

Sodium Chloride.....

INERT INGREDIENTS.

TOTAL.

Potassium peroxymonosulfate.

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 6XD, England Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

SIDE PANEL

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Avian Laryngotracheitis, and Avian Influenza. Fungi (molds and yeasts - Aspergillus flavus, Aspergillus fumigatus and Candida albicans. Bacteria - Streptococcus pyogenes, Campylobacter plyoridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, chicken houses, Ratite production and processing plants.

HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus filmigatus). VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are holes.

Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

SIDE PANEL CONTINUED

SWINE PRODUCTION

CONTROLS: Viruses of Hog Cholera, Porcine Parvo Disease, Vesicular Stomatitis, Pseudorabies, Porcine Reproductive and Respiratory Syndrome (PRRS) Rotoviral Diarrhea, Swine influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Atrophic Rhinitis, Pasteurellosis, Colibaciliosis, Enteritis, Erysipelas, Leptospirosis, Mastitis, Necrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysentery. Fungi (molds and yeasts) Aspergillus flavus, Aspergillus fumigatus and Candida albicans.

VIRKON S is recommended for use in farrowing pens, weaner accommodation, grower accommodation and finisher accommodation and processing plants: VIRKON S at 1% solution is generally suitable for cleansing and disinfecting (use 2% solution for Mycoplasma, Aspergillus flavus and Aspergillus finnigatus).

VIRKON S is recommended for use in fogging (wet misting) operations or as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

EQUINE PRODUCTION APPLICATIONS

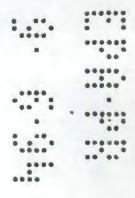
For cleaning and disinfection of all surfaces, equipment, utensils and instruments in Veterinary practices, kennels, stables, catteries, etc.

DIRECTIONS FOR USE

Add the contents of one sachet to one gallon of warm water. In cases of parvovirus challenge, add the contents of two sachets to one gallon of water. Solutions are stable for 7 days. Do not soak metal objects for long periods - 10 minutes is maximum necessary contact time.

CONTROLS

Viruses of African Horse Sickness, Equine Viral Arteritis (Pink Eye), Coital Exanthema, Myeloencephalopathy, Rhinopneumonitis, Equine Contagious Abortion, Equine Papillomatosis, Equine Infectious Anaemia (Swamp Fever) Adenovirus Pneumonia, Equine Influenza (The Cough) and Rhinitis, Bacterial; Clostridial Diarrhea, Salmonellosis, Enteric Colibacillosis, Fistulous Withers (Poll Evil), Contagious Equine Metritis (CEM) Strangles and Glanders. Fungi; Dermatophytosis (Ringworm) and Dermatopyhlosis (Mud Fever).



VIRKON. S

DILUTION CHART

Quantity of	200 00 00 00	and difference
Final Solution	1% Solution	2% Solution
American		
1 galion	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 kgs	4 kgs
125g	6oz	
100g	5oz	
75g	4 02	
50g	3oz	
	2oz	

ioz

Brim full - contains 200g or 7 ounces The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if imitation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh an and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.....

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container away from children. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

ANTEC INTERNATIONAL LTD

Windham Road, Chilton Industrial Estates Sudbury Suffolk C010 OCD, England Tel: (0787) 77305 Telx: 987495 Fax: (0787) 310846

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001



with COMMENTS in EPA Letter Dated

and the same of th

DEC 0 1 1994

Under the Federal Insecticide," Fungicide, and Rodenticide Act as amended, for the pestuade restautered under EPA first, No.



BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals; wruses, Gram positive and Gram negative bacteria, fungi (molds and yeasts), and Mycoplasma. Efficacy was determined in the presence of hard water and organic material.

DIRECTION FOR USE

Federal law prohibits use of this product in a manner inconsistent with its - Ratite

This powder formula is easily diluted for use in-memoral or machine operations.

POULTRY PRODUCTION/RATITE PRODUCTION

VIRKON S is recommended for use in hatcheries, in chicken houses and in Ratte production.

CONTROLS: Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursaf Disease, Laryngotrachettis Avian Influence: Maruk's Disease and Egg Drop Syndrome. Fungi; Aspergillus Illavus, and Candida albicans. Bacteria; Streptococcus pyogenas, Campylobacter pytoridis, Infectious Bronchies, Klebsella pneumonae, Eschenichia coli, Salmonella typhrimurium, Salmonella choleraesus, Paeudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum, Necrotic ententis.

HATCHERIES: VIRNON S at 1% solution is generally suitable for cleaning and disinfecting habiters, setters, evaporative coolers, humidilying systems, calling lans, chicken houses, transfer trucks. trays, and plastic chick boxes (use 23/ solution for Mycoplasma, and Aspergillus flavus).

VIRKON S is recommended for use in logging (wet misting) operations as an adjunct either preceding or following regular cleaning and distribution procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is most using automatic wet loggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickers, leed and water boughs, remove manure and litter and spray floors and side wids with VIRKON'S at 1%. Thoroughly wash wateress and leeders with a 1% solution of VIRKON'S (use 2% solution for Mycoplasma and Aspergillus Bavus). Do-not use to house poultry or employ equipment until the treatment has dried.

SWINE PRODUCTION

CONTROLS: Viruses of Steps Bye, Flog Cholera, Porcine Palve-Disease, Vesicular Stometitis/PRRS) Pseudorabies, Rotaviral Diarrhelea, Swine Influenza, Foot and Mouth Disease and TGE. Bacteria of Arthritis, Meningitis, Alfront Phinitis, Pasteurelloss, Collbacillosis, Enteritis, Erispelas, Loptospirosis, Masteix, Mercrotic Enteritis, Pleuropneumonia, Salmonellosis and Swine Dysontery, Fulgi (molds and yeasts) Aspergillus flavus and Candida albicants.

VIRICON is recommended for use in Farrowing pens, weaker accomodation grower accomodation and finisher accomodation and processing plants: VIRICON S at 1% solution is generally suitable for cleaning and disinfecting (use 2% solution for Mycoplasma and Aspergitus flavus).

VIRICON S is recommended for use in logging (wel-misting) operations ox, as an adjunct either preceding or following regular cleaning shit distributing proceedings. VIRICON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic loggers according to manufacturer's use directions.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the absosphere until surfaces are moist. Allow at least 2 hours before entering area that has been logged.

STORAGE & DISPOSAL: Store in a cool, dry place in lightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash. Aspergillus fumigatus

and

Aspergillus fumigatus

Aspergillus fumigatus

After contact time of 10 minutes, rinse with potable water.

Porcine Respiratory and Reproductive Syndrome

Atrophic

Erysipelas

Aspergillus fumigatus

Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridis Klebsielia pneumoniae Escherichia coli Salmonella typhimunium Salmonella choleraesuis Pseudomonas aeruginosa Staphylococcus epidermidis Mycoplasma gallisepticum Clostridium spp	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Ident's Disease Egg Drop Syndrome	Aspergilus farus Cardida abicans Aspergillus furnigatus

ACTIVE INGREDIENTS

rowssiam berasyma	MOSUMBLE 20.4%		
Sodium Chloride	1.5%	_	
INERT INGREDIENTS	78.4%	۳	ì
TOTAL	100.0%		

Equivalent to 9.75% Available Chlorine

DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792 Made in England by Antec International Limited

VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No. 4822512



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Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST

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....

BACTEFIA-	VIRUSES OF	FUNGI
Streptococcus pyogenes Staphylococcus aureus Klebsiella prieumoniae Escherichia coli Salmonella typhimurium Ralmonella choleraesus Pseudorionas aeruginosa Staprif occides epidermidis Mycoplasmis spp Bordetella Pronchiseptica Pasteurella muitocida Campylobacter spp Eryspelothrix rhusiopathiae aptos pasteurella muitocida Compylobacter spp Clostribum sps Actinobactius pleuropneumoniae Treponema hypodysenteriae	Hog cholera Swine Influenza TGE Blue eye Porcine parvovirus Rolaviral diarriflea Vesicular stomalilis Pseudorabres PRRS (Porcine Reproductive and Respiratory Syndrome)	Aspergillus flavus Candida albicana Aspergillus fumigatus

****EEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

10lbs Net Weight

Distributed By:



301 Baybrook Street, Thomasville, GA 31792 Made in England by Antec International Limited

VIRICON S is a registered trademark of and manufactured by Arrico International Limited U.S. Patent No. 4822512

Virkon, S

DILUTION CHART

Quantity of Final Solution	1% Solution	2% Solution
American 1 gallon 10 gallons 50 gallons	1.3 ounces 13.4 ounces 66.8 ounces	2.7 dunces 26.7 dunces 133.5 dunces





For DISINFECTING use a rate of 7.5 gallons/1000 eq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. it.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhalted. Do not get in eyes, on skin, or on closting. Wear protective clothing and nubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and waste before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelide open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIR: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or whenceng are inoublescome, remove to fresh air and seek medical ablothon.

IF SWALLOWED: Drink premptly a large quantity of water Avoid alcohol. Get immediate medical attention.

NOTICE OF PHYSICIAN: Probable mucosal damage may contratinuicate the use of gaster lavage.



Manufactured for

Durvet Inc. Blue Springs, Missouri, 64015-1-800-821-5570 EPA Reg. No. 62432-1-12281. EPA Est. No. 62432-EN-001

Made in England by Antec International Limited

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 9-28-94 OUT 10-18-94

Reviewed by Michael Nieves	Date 10-18-94
	62432-1
EPA Petition or EUP No.	None
Date Division Received_	9-6-94
Type Product Animal and A	griculture Broad Disinfectant
MRID No(s)	None
Product Manager	R. Douglas (PM 32)
Product Name	Virkon S
Company Name	Antec International
fumigatus a	ion is an application to add croorganisms: Aspergillus nd Porcine Reproductive and Syndrome (PRRS) virus.
Type Formulation	Liquid
Active Ingredients(s)	
Potassium peroxymonosulfate	20.4%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol	62432-1
EPA Petition or EUP No	None
Date Division Received	9-6-94
Type Product Animal and	Agriculture Broad Disinfectant
MRID No(s)	None
Product Manager	R. Douglas (PM 32)
Product Name	Virkon S
Company Name	Antec International

200.0	Introduction:
200.1	Uses:
	See attached proposed label dated 9-6-94.
200.2	Background Information:
	The submission is an application to add additional microorganisms: Aspergillus fumigatus and Porcine Reproductive and Respiratory Syndrome (PRRS) virus.
200.3	Factors Affecting Amount/Type of Data Required:
	None
201.0	Data Summary
	None
201.1	Abstract of Test Reports:
	None
201.2	Brief Description of Tests:
	No efficacy data was submitted with this submission.
201.3	Data Summaries
	None
201.4	Other Summarized Results:
	See Recommendations under 202.0.

202.0 Recommendations

202.1 Efficacy Supported By The Data:

No efficacy data was submitted with this submission because the labeling amendments are not related to human health.

203.0 Labeling:

The labeling amendments to add additional microorganisms: Aspergillus fumigatus and Porcine Reproductive and respiratory Syndrome (PRRS) virus are acceptable.

A.

N

DR. ALAN R. WAGNER Regulatory Affairs and Technical Services

Private Counsultation

4302 S.W. 147th Place Miami, Florida 33185 (305) 553-9017

August 29, 1994

Ms. Ruth G. Douglas (PM32) Antimicrobial Program Branch Registration Division (7505C) U.S. Environmental Protection Agency 401 M Street S.W Washington, D.C. 20460

Subject: Virkon S (EPA Reg. # 62432)

Dear Ms. Douglas

In accordance with our recent telephone coversation, please find for your review "Application For Pesticide Amendment" updating our EPA Master Label application that was submitted on June 24, 1994. We have received a notice from your agency dated July 11, 1994 informing us of receipt of the application of amendment and that it has passed an administrative screen for completeness. It was also determined at this time that the application qualifies for fast tract review and the package will be forwarded to you for review to determine it's acceptability

Also, as we discussed, Ms. Douglas, we hope that the attached updated amendment will be joined with the application amendment of June 24, 1994 so as not to delay the review process.

We have highlighted the additions on the updated Master Label as you requested and have submitted 5 draft labels reflecting the modifications

Thank you for your exnouragement and assistance in expediting the joining of the two amendments and the courtesy extended to me during my visits at your agency and our telephone conversations. I shall be looking forward to our next meeting in Washington.

Sincerely

acan R. Wagner

Alan R. Wagner, D. V.M., M.S. Manager, Regulatory Affairs Agent for Antec International Ltd.

ARW/mw

Attachments

113



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

09/08/94

ALAN WAGNER DR ALAN WAGNER, DVM, MS 4302 SW 147 PLACE MIAMI FL 33185

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: VIRKON S

COMPANY NAME: DR ALAN WAGNER, DVM, MS

OPP IDENTIFICATION NUMBER: 191018 EPA REGISTRATION NUMBER: 62432-1

EPA RECEIPT DATE: 09/06/94

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

2 Wrice

Front End Processing Staff
Information Services Branch
Program Management and Support Division



AMENDMENT

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WITH DATA		ON FOR A		Init.	Date
		ON FOR A	NO DATA	Init.	Date

* Front End Processing determined this application qualifies for fast track review based on registrants claim of "me-too". No screen for substantial similarity is made by the Front End.

103	United Ctates	Environmental Prote		proved			Approval expires OPP Identifier N	
(A) SEP	Office of P	environmental Protei Pesticide Programs (I ashington, DC 2046	H7505C)	X	Registrat Amendm		1910	
A PI	Appli	cation for Pe			Other		1010	TO
		Section I						
1. Company/Product Number	er		2. EPA Product Ma			3. Pro	oposed Classifica	ition
62432 - (Ms. Ruth C	G. D	ouglas			
4. Company/Product (Name	9)		PM#			X	None Re	estricted
Virkon S			32		- 1			
5. Name and Address of Ap Antec Interna Chilton Indus Sudbury, Suff	ational Ltd strial Estate folk C010 6XD		6. Expedited Re (b)(i), my product to: EPA Reg. No					
Check if this	is a new address		Product Name					
		Section I I						
Amendment - Explain b	woled		Final printed Agency lette		in response to			
Resubmission in respon	nse to Agency letter date	ed	"Me Too" Ap					
Notification - Explain be	alow.		Other - expla					
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acan R. Wagner D.U.W. W.S.

3. Title Manager, Regulatory Affairs Agent for Antec Internationa

5. Date

Alan R. Wagner, D.V.M., M.S.

August 29, 1994

116
Yellow - Applicant copy

Ltd.

White - EPA File Copy (original)

2. Signature

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SM, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Nanagement and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

Confidential Statement of Formula (EPA Form 8570-4);
 Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted; 6. Authorization letter where applicable;

7. Matrices where applicable. Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections 1, 11, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

<u>SECTION I</u> - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing

address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency Letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered eroquet. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency Letter date if appropriate. Provide a brief

explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the "Lonfidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.

2. Type of Retail Container - Indicate type of container in which product will be marketed.

- 3. Location of Net Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.

5. Location of Use Directions - Indicate the Location of the use directions for your product.

6. Manner in which tabel is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Only.

Reviewer ID Submission No. Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS File Symbol/Reg. No. 62 432-1 PM 30 Action Code 300 10 Descriptor (Amend/Resultations only) and eral |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / /(C) Certification Packaging / (N) No 7(S) Service Person |20| Registration Type: (R) Non-residential Use Only / / (1) Conditional / / (2) Unconditional (N) Not-Applicable 25 Proposed Classification: |30 Final Classification: / / (R) Restricted / (R) Restricted / / (G) General (N) Not Classified 35 Date on Application: |04 EPA Received Date: 40 Date Received by PM |80 | Hethod of Support: // (1) Cite-All /. / (6) Owner Submission /// (4) Not Applicable // (7) Total Submission / (5) Not Submitted / / (8) Selective Method RESPONSE RESPONSE DATE WE DATE Reviewers Requested: SENT DATE RETURNED CODE CH EF PL DEB NDEB TB EEB **EFGB** 019 219 913 115 FINAL 120 Response Response ACTION Code

29 SEP 1993

Richard J. Otten, Agent for Antec International Ltd. Windham Road Chilton Industrial Estate, Sudbury Suffolk, C0106XD England

Subject: Virkon S

EPA Registration No. 62432-1

Your Labeling Dated December 3, 1992

Dear Mr. Otten:

The amended labeling referred to above, with minor revisions and new company name, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records.

- Place the Storage and Disposal section in the Directions for Use section.
- 2. Submit five copies of the finished labeling before the product is released for shipment bearing the amended labeling.

Submit a letter for our records, on the registrant's company letterhead or notarized, authorizing you to act as their agent in registration matters with EPA.

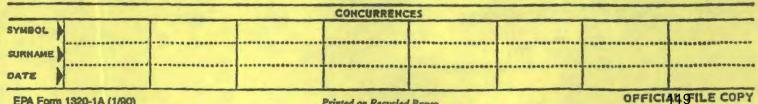
Note that we do not review alternate distributor labels for acceptance.

If you have any questions about these comments, you may call Wallace Powell at 703-305-6938.

Sincerely,

Ruth G. Douglas Product Manager 32 Antimicrobial Program Branch Registration Division (H-7504C)

Enclosure



EPA Form 1320-1A (1/90)

Antec International

V (Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF

Avian Influenza

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis

FUNGI

Aspergillus flevus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	78.1%
TOTAL1	00.0%

Equivalent to 9.75% Available Chlorine

DANGER:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

29 SEP 1993 Under the secret lessection and the secret lessection and the posticide Act and the secret lessection and the secretarily and the secret lessection and the secret lessection and the secret lessection and the secre

Distributed By:

MICROTEC Animal Nutrition, Inc.

301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822512

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, and Avian Influenza. Fungi (molds and yeasts) - Aspergillus flavus and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter pyioridas, Kiebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

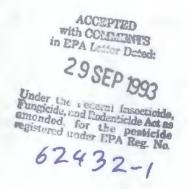
HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma and Aspergillus flavus).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and Aspergillus flavus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



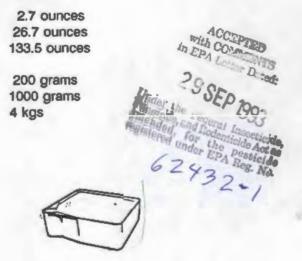


VIRKON® S

2% Solution

DILUTION CHART

Quantity of	
Final Solution	1% Solution
American	
1 gallon	1.3 ounces
10 gallons	13.4 ounces
50 gallons	66.8 ounces
Metric	
10 liters	100 grams
50 liters	500 grams
200 liters	2 kgs
	_



125g 100g 75g 50g 50g 60z 50z 4 oz 30z 20z 10z

Brim full - contains 200g or 7 ounces

The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

F IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

<u>IF SWALLOWED</u>: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attentions. NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

Manufactured for
MICROTEC Animal Nutrition, Inc.
301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

EPA Reg. No. 62432-1

EPA Est. No. 62432-EN-001

by FEPS and <u>must</u> be entered in the PRATS using one of the following codes: 160 - Application for "me-to" registration 170 - Application for registration - old chemical - "Metoo" with additional use. 300 - Amendment - label revision - administrative (no data required). 305 - Amendment - label revision - data required does no need HED/EFED review.		
PAM (ROOM 263) FROM: FRANCES WRICE TYPE OF REGISTRATION FAST - TRACK ACTION (with data without data) This action has been determined to be a fast-track actio by FEPS and must be entered in the PRATS using one of the following codes: 160 - Application for "me-to" registration 170 - Application for registration - old chemical - "Metoo" with additional use. 300 - Amendment - label revision - administrative (no data required). 305 - Amendment - label revision - data required does not need HED/EFED review. 310 - Amendment - added "me-too" Use - no HED/EFED review needed. 345 - Formula change - no HED/EFED review required. REGULAR REGISTRATION (with data/without data) 24C NEW 24C AMENDMENT RESUBNISSION (response to Agency ltr) FIMAL PRINTED LABELS	TO:	PILE ROOM
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

12/10/92

S.R. CRAGG -PHONE: 0787 77305 ANTEC INTERNATIONAL LTD WINDHAM ROAD, CHILTON INDUSTRIAL ESTATE SUDBURY, SUFFOLK 00000

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Product Name: VIRKON S

Company Name: ANTEC INTERNATIONAL LTD.

Application No.: 156034 EPA Reg. No.: 62432-1

EPA Receipt Date: 12/08/92

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

for Team Leader
Front Front Front End Processing Staff Registration Support Branch Registration Division (H7504C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

. WASHINGTON, D.C. 20460

12/10/92

S.R. CRAGG -PHONE: 0787 77305 ANTEC INTERNATIONAL LTD WINDHAM ROAD, CHILTON INDUSTRIAL ESTATE SUDBURY, SUFFOLK 00000

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Product Name: VIRKON S

Company Name: ANTEC INTERNATIONAL, LTD.

Application No.: 156033 EPA Reg. No.: 62432-1

EPA Receipt Date: 12/08/92

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

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If you have any questions, you may contact Ruth Douglas, Product Manager 32, at (703)-305-7964.

Sincerely,

for Team Leader Front End Processing Staff Registration Support Branch Registration Division (H7504C)

RICHARD J. OTTEN

Registration and Regulatory Services

December 3, 1992

Ms. Ruth Douglas
Product Manager, Team 32
Fungicide-Herbicide Branch
Registration Division (H-7505C)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, DC 20460

RE: EPA Registration No. 62432-1 VIRKON-S

Dear Ms. Douglas:

Attached please find five copies of two revised texts for the product cited above.

This product was originally registered by A.H. Robins; EPA Reg. No. 778-91. Several months ago the registration was transferred to the manufacturer, Antec International, Ltd., by EPA and assigned the new number shown above.

Other changes included are:

- 1. Showing Microtec Animal Nutrition as the primary distributor for Antec in the U.S. under the Antec EPA Registration number, not under a supplemental distributor number.
- Showing the company DURVET as a secondary distributor, again using Antec's EPA Registration number only.
- 3. Minor editorial changes such as inserting the word .. "solution" in several places following percentage figures and deleting two microbial species which were listed on the A.H. Robins label.

We will appreciate your review and response as promptly as possible. As you well know, it takes many months to finalize

5116 Wood Valley Drive, Raleigh, NC 27613 Office (919) 846-7860 Telefax (919) 846-2775

Ms. Ruth Douglas December 3, 1992 Page 2

printed labels, package product, etc., and we need to know as soon as possible that no additional changes will be required by EPA.

Sincerely,

Richard J. Otten

U.S. Agent of Record

Antec International, Ltd.

RJO/dgm

Enclosures:

1. EPA Form 8570-1 with Antec Label

2. EPA Form 8570-1 with Durvet Label

cc: Antec International, Ltd. (R. Auchincloss)

Microtec (G. Myers)

Phoenix Regulatory Associates (C.K. Gund)

Durvet

V (Virkon logo)

VIRKON® S BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF

Avian Influenza

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitls

FUNGI

Aspergillus rlavus Candida albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate	20.4%
Sodium Chloride	1.5%
INERT INGREDIENTS	78.1%
TOTAL	00.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN **DANGER**:

See Back Panel for Additional Precautions

11 lbs (5Kg) Net Weight

Agents for Antec:

MICROTEC Animal Nutrition, Inc.

301 Baybrook Street, Thomasville, GA 31792, phone 912-225-1182

VIRKON S is a registered trademark of and manufactured by Antec International Limited

U.S. Patent No. 4822312

سيول خام مي

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis and Avian Influenza. Fungi (molds and yeasts) - Aspergillus flavus and Candida albicans.

Bacterla - Streptococcus pyogenes, Campylobacter pyioridas, Kiebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

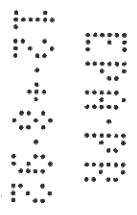
HATCHERIES: VIRKON S at 1% solution is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% solution for Mycoplasma and Aspergillus flavus).

VIRKON S is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. VIRKON S at 1-2% solution is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% solution for Mycoplasma and Aspergillus flavus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

FOR AIR SANITIZING: Use VIRKON S at 1-2% solution. Fog the atmosphere until surfaces are moist. Allow at least 2 hours before entering area that has been fogged.

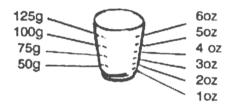
PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.



VIRKON® S

DILUTION CHART

1% Solution	2% Solution
1.3 ounces	2.7 ounces
13.4 ounces	26.7 ounces
66.8 ounces	133.5 ounces
100 grams	200 grams
500 grams	1000 grams
2 kgs	4 kgs
	1.3 ounces 13.4 ounces 66.8 ounces 100 grams 500 grams



Brim full - contains 200g or 7 ounces



The measure cap holds when filled level 500g or 17.5 ounces.

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medica attention.

FSWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.
NOTICE OF PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

Manufactured for:
DURVET, Inc.
Blue Springs, Missouri 64015

EPA Reci. No. 62432-1

EPA Est. No. 62432-EN-001

RICHARD J. OTTEN

Registration and Regulatory Services

December 3, 1992

Ms. Ruth Douglas
Product Manager, Team 32
Fungicide-Herbicide Branch
Registration Division (H-7505C)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
Washington, DC 20460

RE: EPA Registration No. 62432-1 VIRKON-S

Dear Ms. Douglas:

Attached please find five copies of two revised texts for the product cited above.

This product was originally registered by A.H. Robins; EPA Reg. No. 778-91. Several months ago the registration was transferred to the manufacturer, Antec International, Ltd., by EPA and assigned the new number shown above.

Other changes included are:

- Showing Microtec Animal Nutrition as the primary distributor for Antec in the U.S. under the Antec EPA Registration number, not under a supplemental distributor number.
- 2. Showing the company DURVET as a secondary distributor, again using Antec's EPA Registration number only.
- 3. Minor editorial changes such as inserting the word "solution" in several places following percentage figures and deleting two microbial species which were listed on the A.H. Robins label.

We will appreciate your review and response as promptly as possible. As you well know, it takes many months to finalize

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Ms. Ruth Douglas December 3, 1992 Page 2

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Sincerely,

Richard J. Otten

U.S. Agent of Record

Antec International, Ltd.

RJO/dgm

Enclosures:

1. EPA Form 8570-1 with Antec Label

2. EPA Form 8570-1 with Durvet Label

cc: Antec International, Ltd. (R. Auchincloss)

Microtec (G. Myers)

Phoenix Regulatory Associates (C.K. Gund)

(A)	United Star		Protection Agency		Registr	ation	OPP Identifier	Number
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		Sect	ion I					
I. Company/Product Numb	per	0000	2. EPA Product I	Manager		3. Pi	roposed Classific	cation
EPA Reg. No.			Ruth Dougl	lass				
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		Sectio	- AATIM					
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Resubmission in respo	onse to Agency letter	dated	"Me Too"	Applicatio	и.			
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PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

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INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resultains for applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

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2. Confidential Statement of Formula (EPA Form 8570-4);

3. Formulator's Exempt on Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted;

6. Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Hanager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Keviet - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to the product of the contract o

the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration to the behavior and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency for the Ammission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of extmission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the "Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory.
6. EPA Use Only.

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5. Three copies of any data submitted;

6. Authorization letter where applicable;

7. Matrices where applicable.

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SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit suthorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific

FM-registered product. This section is <u>not to be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief ** explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the •••Confidential 6tatement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach · a separate page if additional space is needed.

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 Indicate the size of the individual packets and number per retail container.
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5. Location of Use Directions - Indicate the location of the use directions for your product.

6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

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1-5. Self-explanatory.

6. EPA Use Only.

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			Submission	No. B	40884	6
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This is an accepted submission. One copy of the PPC diagnosis and one of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a partially accepted/rejected submission. A copy of the PPC diagnosis and of the annotated bibliography (if applicable) are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

A.H. ROBINS CO. INC. P. O. BOX 26609 1405 CUMMINGS DR. RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/15/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

120924-00

A. H. Robins Company 1407 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 FAX (804) 257-2670 Telephone (804) 257-2000



Ms. Ruth G. Douglas
Acting Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

November 6, 1991

Re: EPA Registration 778-91
Submission of Product
Chemistry for the Product
VirKon S (Disinfectant)

Dear Ms. Douglas:

VirKon S, EPA Registration No. 778-91, is approved by EPA as a broad spectrum disinfectant.

Enclosed, in triplicate, under Guideline No. 63-17, is a Product Chemistry Study. This study was originally submitted on May 31, 1991, and was rejected by EPA as not being in the proper format. It was resubmitted on October 15, 1991. 4764740

Today we received notification that the study was again rejected for not containing the proper flagging statement. We have added the flagging statement and hereby resubmit this study for your review.

The submitter, A. H. Robins Company, 1407 Cummings Drive, P. O. Box 26609, Richmond, VA 23261-6609, has conducted this study on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

Please call me at (804) 257-2035 if there are any questions.

Sincerely,

Donald L. Gilbert, B.S., M.B.A.
Director, Regulatory Affairs
and Product Development
Special Products Division

Enclosures

N-3

			Reviewer I	D	R	Dougla	G
			Submission	No.	52	106180	
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U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

9 1 NOV 1991

A.H. ROBINS CO. INC. P. O. BOX 26609 1405 CUMMINGS DR. RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/22/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

You must include the appropriate flagging statement for this study as specified in 40 CFR 158.34. This statement must be signed and dated by an authorized representative of the company.

A. H. Robins Company 1407 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 FAX (804) 257-2670 Telephone (804) 257-2000



Ms. Ruth G. Douglas
Acting Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

October 15, 1991

Re: EPA Registration 778-91
Submission of Product
Chemistry for the Product
VirKon S (Disinfectant)

Dear Ms. Douglas:

VirKon S, EPA Registration No. 778-91, is approved by EPA as a broad spectrum disinfectant.

Enclosed, in triplicate, under Guideline No. 63-17, is a Product Chemistry Study. This study was originally submitted on May 31, 1991, and was rejected by EPA as not being in the proper format.

The submitter, A. H. Robins Company, 1407 Cummings Drive, P. O. Box 26609, Richmond, VA 23261-6609, has conducted this study on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

Please call me at (804) 257-2035 if there are any questions.

Sincerely,

Donald L. Gilbert, B.S., M.B.A. Director, Regulatory Affairs and Product Development Special Products Division

Enclosures

PM 32

anis is an accepted submission. One copy of the PPC diagnosis and one of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a rejected stubmission. A copy of the FTC diagnosis and of the annotated bibliography (if applicable) are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

WWDDGE Reviewer ID 5397319 Submission No. Data Package No. CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENIMENTS File Symbol/Reg. No. 778-9/ PM 32 Action Code 345 10 Descriptor (Amend/Resubmissions only) _ stability data |5 | Intrastate Call-in / (Y) Yes |15 | Child-resistant / (C) Certification Packaging (N) No /(S) Service Person 20 Registration Type: / (R) Non-residential Use Only / (1) Conditional / (2) Unconditional / (N) Not-Applicable 25 Proposed Classification: 30 Final Classification: / (R) Restricted // (R) Restricted // (G) General (N) Not Classified 35 Date on Application: 04 EPA Received Date: 40 Date Received by PM [80] Method of Support: / (1) Cite-All / / (6) Owner Submission SEP 25 1991 /X/ (4) Not Applicable // (7) Total Submission / / (5) Not Submitted / / (8) Selective Method RESPONSE DATE DUE DATE RESPONSE Reviewers Requested: SENT DATE CODE RETURNED DATE CH EF PL DEB NDEB TB EEB **EFGB** Response 35 115 FINAL 120 Response ACTION Code 145 N(N) No 75-DAY RESPONSE DUE DATE: / /(Y) Yes

Mr. Donald L. Gilbert
A. H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

SEP 25 1991

Dear Mr. Gilbert

Subject: VirKon S

EPA Registration No. 778-91 Your Letter Dated May 31, 1991

Your submission of storage and stability data for the subject product has completed review. The following comments apply.

The storage and stability data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

The 52 week (12 months) storage and stability data at ambient room temperature (25°C) is in compliance with 40 CFR part 158.190 guidelines Ref. No. 63-17. The data satisfies the one year storage stability data requirement and is acceptable.

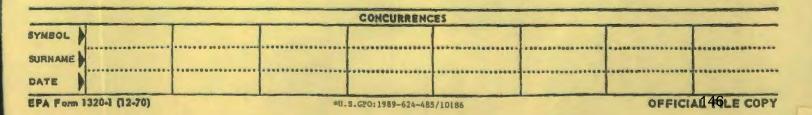
The product was tested up to 128 weeks and appears to be stable in available chlorine.

The data were, however, inadvertently reviewed without being assigned a MRID number. The data are being forwarded for assignment of a MRID number and the Agency will send notification when the data package is complete.

If you have any questions, please call Bill Wooge at (703) 557-1295.

Sincerely yours,

Ruth G. Douglas
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7504C)



DP BARCODE: D165117

SUBMISSION: S397319 DATA PACKAGE RECORD DATE: 06/14/91

BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 345 TECH-FORMULA CHANGE AMND

CHEMICALS: 063604 Potassium peroxymonosulfate 20.4000%

013905 Sodium chloride

01.5000%

ID#: 000778-00091 VIRKON S

COMPANY: 000778 A. H. ROBINS COMPANY INC

703-557-3964 ROOM: CM2 PRODUCT MANAGER: 32 WALTER FRANCIS 711-E

PM TEAM REVIEWER: RUTH DOUGLAS 703-557-3842 ROOM: CM2 711G

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 165117 EXPEDITE: N DATE SENT: 06/14/91 DATE RET.:

CHEMICAL: 063604 Potassium peroxymonosulfate P TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 07/29/91 CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT DIV : RD BRAN: RSB SECT: PCRS / / REVR: CONTR:

* * * DATA REVIEW INSTRUCTIONS * * *

REVIEW STABILITY DATA.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

Product Chemistry Review RSB

PA Reg. No. or File Symbol	778-91
Daca Division Received	6-4-91
Produces Manager No.	32 (Francis)
Product Name	Vickon S
Company Name	A. H. Robbins Co., Inc.
compliance with Ref. No. 63-17 it stability data Product was test to be stable in	k (12 months) storage and stability t room temperature 25°C is in HO CFR part 158. 190 buildbins t satisfies one year storage requirement and is acceptable. to up to 128 weeks and appears available chlorine. does not have MRID rumber.

148 -

anna Skapars

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 Cable Robinter/Telex 828-370 Telephone (804) 257-2000

A-H-ROBINS

Mr. Walter C. Francis
Product Manager (32)
U.S. Environmental Protection
Agency
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

May 31, 1991

Re: EPA Registration 778-91
Submission of Stability for
the Product VirKon S
(Disinfectant)

Dear Mr. Francis:

VirKon S is approved by EPA as a broad spectrum disinfectant.

The A. H. Robins company have conducted the stability on VirKon S in addition to what was in the original submission. All work was done at 25 degrees Centigrade.

The following is enclosed in triplicate:

- 1) 68-week stability for VirKon S Lot 81109-73 (marketed material) showing the product is stable.
- 2) 68-week stability for VirKon S Lot 81109-74 (marketed material) showing the product is stable.

The stability of the above two lots is continuing.

In addition to the above, I am submitting other stability work that was accomplished with the product VirKon S without the color and perfume:

- 3) 128-week stability for VirKon S lot 03809160B (in the marketed container) showing the product is stable.
- 4) 104-week stability for VirKon S lot 02809160B (in the marketed container) showing the product is stable.
- 5) 128-week stability for VirKon S lot 01809160B (in the marketed container) showing the product is stable.

Mr. Walter C. Francis May 31, 1991 Page 2

6) 52-week stability for VirKon S lost 01809160A (in the marketed container) showing the product is stable.

Please call me at (804) 257-2035 if there are any questions.

Sincerely yours,

Donald L. Gilbert, B.S., M.B.A. Director, Regulatory Affairs and

Product Development Special Products Division





Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacier pyforidas (loebileta pneumoniae Escherichia coli Salmonella typhimurium Salmonella dioletraesulis Pseudomonas aeruginosa Staphyloccoccus aureus Staphyloccoccus epidermidis Mycoplasma gallisepticum	Newcastle Disease infectious Bronchitis infectious Bursal Disease Alian Laryngorracheitis Alian Influenza Marek's Disease	Aspergillus flavus Aspergillus fumigatus Candida altocans

ACTIVE INGREDIENTS

Pot	tassium perguymonosulfate	20.49
	dum Chloride	
INERT	INGREDIENTS	76.19
TOTAL		T00.01

Equivalent to 9.75% Available Chlorine

DANGER:

See Back Panel for Additional Precautions

11lbs (5kg) Net Weight

AGRI BIO

Agri-Bio Corp., a subsidiary of A.H. Robins Company, 966 Dorsey St, Galnesville, GA 30501, phone 1-800-AGRI-BIO [247-4246]

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patterit No: 4822512

Virkon, S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotrachettis, Avian Influenza, and Marek's Disease.

Fungl (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida albicans.

Bacheria - Streptococcus pyogenes. Campylobiccier pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhilmunum, Salmonella choleraesuis, Pseudomonas seruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRIKON \$ is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes fuse 2% for Mycoplasma, Aspergillus flavus, and Aspergillus flavus, and

BRONLER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walfs with VIRKON S at 1%. Thoroughly wash waiterers and feeders with a 1% solution of VIRKON S (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus flavus, and Aspergillus flavus, and potable water. Do not use to house pouttry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and deaning walls, ceilings, and floors spray at a dilution of 1%.

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

virkon.S

DILUTION CHART

OUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
f gallon	1.3 aurices	2.7 punces
10 gallors	13.4 ounces	26.7 Dunces
50 gallons	66.8 cunces	133.5 ounces
Metric		
10 liters	100 grams	200 grams
SO liters	500 grams	1000 grams
200 Mers	2 lus	4 Accs





Brim fult - contains 200g or 7 ounces

The measure cap holds when filled level 500g or 17.5 ounces.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft.
For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes storn burns and irreversible eye damage. Harmful if swallowed, absorbed through sloin, or inhaled. Do not get in eyes, on skin. or on diothing. Wear protective clothing and nubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated diothing and wash before reuse.

Practical Treatment

IF IN EYEs: Hold eyelids open and flush with a steacly, gentle stream of water for 15 minutes. Get prompt medical attention. IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

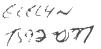
IF INHALED or symptoms of coughing, cholung, or wheezing are IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get Immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may

contraindicate the use of gastric lavage.

Manufactured for

Agn-Bio Corporation, 966 Donley Street, Gainesville, Georgia 30501 U.S.A. EM Reg. No. 778-91-63690. EPA Est. No. 62432-EN-001





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

SEP 4 PA

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Ŀ

Mr. Richard J. Otten PHOENIX REGULATORY ASSOCIATES, LTD. 21525 Ridgetop Circle, #240 Steding, VA. 22170

Agent for: ANTEC INTERNATIONAL LTD.

Chilton Industrial Estate Sudbury, Suffolk CO10 6XD

ENGLAND

Transfer of Pesticide Registrations From Subject:

Company Number 778 to 62432

Dear Mr. Otten:

Pursuant to your request in your letter and transfer agreement of June 11, 1992 (rec'd 8/18/92), we have approved the transfer of the following registration from A.H. ROBINS COMPANY, INC., company number 778, to ANTEC INTERNATIONAL LTD., company number 62432.

The effective date of this change is August 27, 1992.

	Common	Old EPA	New EPA
Registered Products	Chemical Name	Reg. No.	Reg. No.
Virkon S	Potassium Peroxy-	778-91	62432-1
-	monosulfate		_

The effective date of issuance of the new EPA registration number is August 27, 1992. You should indicate the new company designation and new EPA Req. No. on the labeling at the next If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, you must maintain complete and accurate records which identify by batch number, lot number or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

You are required to contact your local EPA'Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Reg. No. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Reg. No. listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as they had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The maintenance fee is determined based solely on the total number of active sec. 3 and sec. 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be cancelled.

By copy of this letter we are informing A.H. ROBINS COMPANY, INCORPORATED of these changes.

Sincerely,

James A. Tompkins
Acting Section Head for
Administrative Processing Section
Registration Support Branch
Registration Division (H7505C)

cc: A.H. ROBINS COMPANY, INCORPORATED

Reviewer ID Submission No. S397029

	NS FOR REGISTRAT			
File Symbol/Reg. No. 7				
10 Descriptor (Amend/Res	submissions only)	COPY OF	LAST ST	AMPED LAB
Intrastate Call-in	(Y) Yes 1	Child-resista Packaging	ant //(C) Certification
7_	(N) No	rackaging) Service Person
20 Registration Type:				Non-residential
(1) Conditional	/ (2) Und	conditional	/ / (N	Use Only
Proposed Classificati	on: 30 Final C	lassification:		Not-Applicable
(R) Restricted	(R) Rest	ricted		
(G) General	(N) Not	Classified		
35 Date on Application			40 Date Rec	
012991	060	691	060	691
80 Method of Support:	75	AL IR	s no	DAI IR
(1) Cite-All	77 (6) Omor	Submission		
(4) Not Applicable		Submission		
(4) Not Applicable (5) Not Submitted				
(5) NOE SUGRICEED	(6) Select	tive method		
	DAMES CONT.	Dim	DECEMBED	DECEMBER
	DATE DUE SENT DATE	DATE RETURNED	RESPONSE CODE	RESPONSE DATE
Reviewers Requested:				
CH CH				
CH EF				
CH EF PL				
CH EF PL DEB				
CH EF PL DEB NDEB				
Reviewers Requested: CH EF PL DEB NDEB TB				

MEMORANDUM OF CALL Previous editions usab	le
TO: V. Deutch	
YOU WERE CAILED BY- YOU WERE VISITED BY-	2
OF (Organization)	-
PLEASE PHONE S46-8427	4
WILL CALL AGAIN IS WAITING TO SEE YOU RETURNED YOUR CALL WISHES AN APPOINTMEN	
MESSAGE -178-91	_
111 to so of the	
ants a copy of	
RECEIVED BY COULT BATE 399/TIME,	2
63-110 NSN 7540-00-634-4018 STANDARD FORM 63 (Rev. 8-8)	20

mailed to string. W.

mme

Reviewer ID 5
Submission No. S381847
Data Package No. D155614

CODING FORM FOR APPLICATIONS FOR REGIST			
File Symbol/Reg. No. 778-91			0
10 Descriptor (Amend/Resubmisions on)	y) Fogging Use	,	-
5 Intrastate Call-in (Y) Yes	15 Child-resistant Packaging	(C)	Certification
/_/ (N) No	rackaging		Service Person
20 Registration Type:		(R)	Non-residential Use Only
	Unconditional	// (N)	Not-Applicable
25 Proposed Classification: 30 Fina	al Classification:		me uphromie
(R) Restricted (R)	Restricted		
/ (G) General / (N)	Not Classified		
35 Date on Application: 04 EPA I		Date Recei	
0 8 2 9 9 0 0 9 MO DAY YR MO	0 4 9 0 0	0 9 1 D	NY YR
80 Method of Support:			
// (1) Cite-All // (6) O	mer Submission		
/ (4) Not Applicable / (7) To			
// (5) Not Submitted // (8) Se			
		RESPONSE	RESPONSE
		CODE	DATE
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NDEB		Ha	
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EFGB			1000
115 FINAL Response 38 ACTION Code	120 Response	MD DAY	6 1990 M
75-DAY RESPONSE DUE DATE: //(Y) Yes	(N) No		160

OCT 2 6 1990

Mr. Donald L. Gilbert
Research & Development and
Regulatory Affairs
A.H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Dear Mr. Gilbert:

Subject: Virkon S

EPA Registration No. 778-91 Your Amendment Dated August 29, 1990

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Pungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Submit five copies of the Limished label.

If you have any questions, please contact Arvella Farmer at (703) 557-6939.

Sincerely yours,

208

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7505C)

Enclosure

	54055:	I:A-4/A-29/	A-118:WP5.0	: COMEURAENO	Sk:KENCO:	10/14/90:DD	:in:de	
SYMBOL								
SURNAME				-				
DATE	***************************************	1000044480-44440		-				
EPA Form	1320-1 (12-70)			01,00		The same	OFFICE	ALGILE COPY

45,8, GPO : 1986-159-319



Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridas Kletsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella typhimurium Selmonella dholeraesuis Pseudomonias aeruginosa Staphylocococus aureus Staphylocococus epidermidis Mycoplasma gallisepticum	Newcastle Disease Infectious Brandhitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease	Aspergillus flavus Aspergillus fumigatus Candida albicaris

ACTIVE INGREDIENTS

A THE THE PARTY OF			
Potassium peroxymonosulfate	20	4%	
Sodium Chloride	1	5%	١
INERT INGREDIENTS			
TYTEM			ı

Equivalent to 9.75% Available Chlorine

DANGER:

See Back Panel for Additional Precautions

11lbs (5kg) Net Weight

DISTRIBUTED BY



Agri-Blo Corp., a subsidiary of A.H. Robins Company, 966 Dorsey St, Gainesville, GA 30501, phone 1-800-AGRI-8IO (247-4246)

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No: 4822512

Virkon, S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals; viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis. Infectious Bursal Disease, Laryngotrachettis, Awan Influenza, and Marek's Diseases

Fungi (moids and yeasts) - Aspergillus flavus, Aspergillus furrigatus, and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter pylondas, Klebsiella pneumoniae, Eschenchia coli, Salmonella typhimurium, Salmonella choleraesurs, Pseudomonas seruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

MATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxies (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus finitiation).

Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S Juse 2% for Mycoplasma. Aspergillus flavus, and Aspergillus furnigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, cellings, and floors spray at a dilution of 1%.

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

Virkon, S

DILUTION CHART

OUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
1 gallon	I.3 ounces	2.7 ounces
fill gallons	13.4 ounces	26.7 oursees
50 gallons	66.8 dunces	133.5 ourses
Metric		
10 Aters	100 grams	200 grams
50 fiters	500 grams	1000 grams
200 libers	2 6.00	4 logs





Brim full - consalns 200g or 7 ownces

The measure cap holds when filled level 500g or 17.5 ourices.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightity dosed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective dothing and rubber gloves. Avoid breathing dust. Wear gloggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

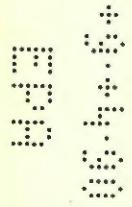
IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention. IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical abention. IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gaetric lavage.

Manufactured for

Agri-Bio Corporation, 966 Dorsey Street, Gaineswile, Georgia 30501 U.S.A. 598 Reg. No. 778-91-43690. E98 Est. No. 62482-EN-001



DP BARCODE: D155614

CASE: 001751 DATA PACKAGE RECORD SUBMISSION: S381847 BEAN SHEET

DATE: 09/12/90

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: TECHNICAL - ADDED "ME TOO" USE AMENDMENT

CHEMICAL: 013905 Sodium chloride

ID#: 000778-00091 VIRKONS

COMPANY: 000778 A. H. ROBINS COMPANY, INC.

PRODUCT MANAGER: 32 WALTER FRANCIS
PM TEAM REVIEWER: WALTER FRANCIS 703-557-3964 ROOM: CM#2 711E 703-557-3964 ROOM: CM#2 711E

RECEIVED DATE: 09/04/90 DUE OUT DATE: 12/03/90

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 155614 EXPEDITE: N DATE SENT: 09/12/90 DATE RET.: / /

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 10/27/90

DATE IN ASSIGNED TO

DATE IN REVR : WCAMPBEL

LABEL: Y

/ /

CONTR:

BRAN: AB SECT: EETES

DIV : RD

ASSIGNED TO

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review the additional use for fogging (misting).

THERE ARE NO ADDITIONAL DATA PACKAGE RECORDS

accepted W/o Comment

165

DP BARCODE: D155614

SECT: EETES

CASE: 001751 DATA PACKAGE RECORD SUBMISSION: S381847 BEAN SHEET

DATE: 09/17/90 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: TECHNICAL - ADDED "ME TOO" USE AMENDMENT

CHEMICAL: 013905 Sodium chloride

ID#: 000778-00091 VIRKONS

COMPANY: 000778 A. H. ROBINS COMPANY, INC.

PRODUCT MANAGER: 32 WALTER FRANCIS
PM TEAM REVIEWER: WALTER FRANCIS 703-557-3964 ROOM: CM#2 711E 703-557-3964 ROOM: CM#2 711E

RECEIVED DATE: 09/04/90 DUE OUT DATE: 12/03/90

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 155614 EXPEDITE: N DATE SENT: 09/12/90 DATE RET.: / /

DP BARCODE: 155614 EXPEDITE: N
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 10/27/90 CSF: Y
ASSIGNED TO
DATE IN
ASSIGNED TO LABEL: Y DATE IN

ASSIGNED TO DATE IN / / DIV : RD REVR : EMITCHEL // BRAN: AB CONTR:

* * * DATA PACKAGE REVIEW INSTRUCTIONS * * *

Please review the additional use for fogging (misting).

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH DATE OUT DUE BACK INS CSF LABEL 155631 AB 09/12/90 10/27/90 Y Y Y 155631

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 09-04-90 OUT 09-13-90

Reviewed By_	Comily H. Mi	itchell Water 09-13-90	
		mbol 778-91	
EPA Petition	or EUP No	None	
Date Division	n Received _	09-12-90	
Type Product	(s)	General Disinfectant	
Data Accessi	on No.(s)		
Product Mgr.	No.	PM 32 (Francis)	
Product Name	(s)	VIRKON® S	
Company Name	(s)	A. H. Robins Company, Inc.	
Submission P	urpose	Label Amendment	
Chemical & F	ormulation _	Powder	
Active Ingre	dient(s):		8
		fate	0.4

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol	778-91	
Date Division Received	09-12-90	
Data Accession No.(s)		
Product Manager No.	PM 32 (Francis)	
Product Name	VIRKON® S	
Company Name	A. H. Robins Company, Inc.	
202 0 Pagamandations		

202.0 Recommendations

203.0 Labeling

The fogging application claim as a adjunct is an acceptable label claim.

No adverse comments on the new label.

TO PRODUCT MANAGER 32, Mr. Frances
DATE: 9-7-90

FAST - TRACK ACTION

This action has been determined to be a fast-track action by the feps and <u>must</u> be entered in the OLTS using one of the following codes:

- 160 Application for "me-too" registration
- 170 Application for registration old chemical "Me-too" with additional use.
- 300 Amendment label revision administrative (no data required).
- 305 Amendment label revision data required does not need HED/EFED review.
- 310 Amendment added "me-too" Use no HED/EFED review needed.
- 345 Formula change no HED/EFED review required.

09/07/90

Product Name: VIRKON-S Company Name: A. H. ROBINS COMPANY Application No.: 128573 EPA Reg. No.: 778-91 EPA Receipt Date: 09/04/90

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before December 24, 1988. Rowever, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Jeff Kempter, Product Manager 32, at (703)-557-3964.

Sincerely,

Team Leader

Pront End Processing Staff Registration Support Branch Registration Division (87504C)

49504C

Form Approved. OMB No. 2070-0060. Approval expire 8-30-90. Please read instructions and notice on reverse before completing form. United States Environmental Protection Agency Office of Pesticide Programs (TS-767) Washington, DC 20460 OPP Identifier Number 28573 Registration **Application for Pesticide:** Amendment Section 4. Proposed Classification 2. Date 3. Product Manager Company/Product Number Restric-778-91 Walter Francis (32) X General August 29, 1990 5. Name and Address of Applicant (Include ZIP Code) A. H. Robins Company 1405 Cummings Drive P.O. Box 26609 Richmond, Virginia 23261-6609 Check if this is a new address 6. Product Name VTRKON-S Section II - Amendment Information Date of Letter 1. Subject Resubmission in response to Agency letter Final printed label in response to Agency letter X Other (explain below) PLACE FOGGING (MISTING) ON APPROVED LABEL Section III 2. Type of Container 1. Material This Product Will Be Packaged In Water-Soluble Packaging Child-Resistant Packaging Unit Packaging Metal X No X X No Yes Yes **Plastic** If "Yes," H "Yes." Glass Unit package wgt No. per container Package weight No. per container Paper Other (Specify) 3. Location of Net Contents Information 4. Size(s) of Retail Container Container 6. Manner in Which Label Is Affixed To Product 5. Location of Label Directions Lithograph Other (Specify) Paper glued On Label Stenciled On material accompanying product Section IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application) Name Donald L. Gilbert Title Director, Product Development and Regulatory Telephone No. (Include Area Code) 6. Date Application Received (Stamped) Affairs, Special Products Division (804) 257-2035 Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. 3. Title Director, Product 2. Signatur Development and Regulatory Affairs Typed Name 5. Date Signed 8-29-90 Donald L. Gilbert

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

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- Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
- 2. Confidential Statement of Formula (EPA Form 8570-4).
- 3. Five copies of draft labeling.
- 4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an 8 $1/2 \times 11$ inch file. Mockup labels significantly smaller than 8 $1/2 \times 11$ inches should be mounted on 8 $1/2 \times 11$ inche paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A , for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block & Check the appropriate action for which you are submitting this form.

Section I This Section must be completed for both Registration and Amended Registration actions.

- Company/Product Number Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establish-
- ment. If application is for an amendment, insert the registra-
- 2. Date Fill in the appropriate date.
- Product Manager If known, fill in the name and number of the Product Manager.
- 4. Alterposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

 Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Specify the net contents of all retail containers for your product.
- Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product,
- Manner in which label is affixed to product Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
- 6. EPA Use Only.



Form Approved. OMB No. 2070-0060. Approval expires 6-30-90. Please read instructions and notice on reverse before completing form. United States Environmental Protection Agency Office of Pesticide Programs (TS-767) Washington, DC 20460 **OPP Identifier Number** Registration **Application for Pesticide:** Amendment Section 3. Product Manager 4. Proposed Classification Company/Product Number 2. Date Restric-August 29, 1990 Walter Francis (32) General 5. Name and Address of Applicant (Include ZIP Code) H. Robins Company 1405 Cummings Drive P.O. Box 26609 Richmond, Virginia 23261-6609 Check if this is a new address 6. Product Name VIRKON-S Section II - Amendment Information Date of Letter 1. Subject Final printed label in response to Agency letter Resubmission in response to Agency letter Other (explain below) PLACE FOGGING (MISTING) ON APPROVED LABEL Section III 2. Type of Container 1. Material This Product Will Be Packaged In Water-Soluble Packaging Child-Resistant Packaging Unit Packaging Metal Plastic Yes H "Yes," If "Yes." X Yes Glass No. per container Paper Unit package wgt Package weight No. per container Other (Specify) 3. Location of Net Contents Information 4. Size(s) of Retail Container Container 5. Location of Label Directions 6. Manner in Which Label Is Affixed To Product Other (Specify) Lithograph Paper glued On Label Stenciled On material accompanying product Section IV 1. Contact Point (Complete items directly below for identification of Individual to be contacted, if necessary, to process this application), Name Donald L. Gilbert Telephone No. (Include Area Code) 6. Date Application Received (Stamped) Title Director, Product Development and Regulatory (804) 257-2035 Affairs, Special Products Division Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. 2. Signature 3. Title ni rector, Product Development and Regulatory Affairs 5. Date Signed Typed Name 8-29-90 Donald L. Gilbert

Sent 1

Paperwork Reduction Act Notice and Instructions

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- • Ment. If application is for an amendment, insert the registra-
- 2. Date Fill in the appropriate date.
- 8. Product Manager If known, fill in the name and number of the Product Manager.
- Proposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

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- 1-5. Self-explanatory.
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Development and Regulatory Affairs

5. Date Signed

Gilbert

Signature

4. Typed Name

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- 2. Product Manager If known, fill in the name and number of the Product Manager.
- 4. Proposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

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- 1-5. Self-explanatory.
- 6. EPA Use Only.

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 Cable Robinter/Telex 828-370 Telephone (804) 257-2000

A-H-ROBINS

Mr. Walter C. Francis
Product Manager (32)
U.S. ENVIRONMENTAL PROTECTION
AGENCY
Antimicrobial Programs Branch
Registration Division (H-7504C)
Washington, DC 20460

August 29, 1990

EPA Registration: 778-91

RE: SUBMISSION OF AMENDED APPLICATION FOR REGISTRATION OF VIRKON-S (AMENDED LABEL - DIRECTIONS FOR USE IN FOGGING APPLICATIONS)

Dear Mr. Francis:

Virkon-S is approved by EPA as a broad spectrum disinfectant. In recent days, I have been in telephone contact with Mr. Wallace Powell asking for clarification on us using Virkon-S in fogging (misting) applications. The response was that consideration can be given to labeling bearing recommendations for fogging applications of chemicals provided that directions are given limiting the application of such procedures to use as an adjunct to acceptable cleaning and disinfecting. Applications prior to manual cleaning amd disinfecting operations or subsequesnt to such operations are considered adjuncts to such operations. Mr. Powell stated that we should file an amended label and no efficacy or other data would be required.

The following is enclosed in requesting an amendment to our approved label requesting fogging (misting):

1.) EPA Form 8570-1, EPA Application for Pesticide (Amendment)

2.) Five (5) copies of the proposed labeling.

If there are any questions, please call me at (804) 257-2035. •

Sincerely yours,

Donald L. Gilbert, B.S., M.B.A.

Director, Regulatory Affairs and Product Development

....





BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and DisInfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridas Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella choleraesus Pseudomonius aeruginosa Staphyloccoccus auteus Staphyloccoccus auteus Staphyloccoccus auteus Mycopiasma gallisepticum	Newcastle Disease Infectious Bronchitts Infectious Bursal Disease Avian Lanyngotrachettis Avian Influenza Marek's Disease	Aspergillus flavus Asperdillus fumigatus Candida albicans

ACTIVE INGREDIENTS

LETTAE HAGINEPICTALS		
Potassium peroxymonosulfate	20	49
Sodium Chieride		
INERT INGREDIENTS	.78	.196
TOTAL	00	01

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11lbs (5kg) Net Weight

DISTRIBUTED BY

AGRI-BIO

Agri-Blo Corp., a subsidiary of A.H. Robins Company, 966 Dorsey St., Gainesville, GA 30501, phone 1-800-AGRI-BIO (247-4246)

In Georgia call collect 404-536-0111

VIRKON \$ is a registered trademark of and manufactured by Antec International Limited U.S. Patent No: 4822512

Virkon, S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals viruses, gram positive and gram negative bacteria, fungl (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitrs, Infectious Bursal Disease, Lanyngotrachettis, Avian Influenza, and Marek's Disease.

Pungl (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebslella pneumoniae, Eschenchia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas seruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON 5 is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON 5 at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, celling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus flavus).

BROLER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and littler and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S [use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus flavus, and Aspergillus flavus, and potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and deaning walls, cellings, and floors spray at a dilution of 1%.

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

Virkon, S

DILUTION CHART

PINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
I gatton	1.3 ounces	27 ounces
ID gallons	13.4 ounces	26 7 ounces
SO galtons	66.B aunces	133 5 ourices
Metric		
10 fibers	100 grams	200 grams
50 Abers	500 grams	1000 grams
200 htters	2 kgs	4 logs





The measure cap holds when filled level 500g or 17.5 ounces.

FOR DISINFECTING use a rare of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - Store in a cool, dry place in tightly closed container. Always replace lid after use Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhalted. Do not get in eyes, on skin, or on clothing. Wear protective dothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

IF IN EYES. Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention. IF ON SKIN: Wash with plenty of soap and water. Get medical attention if Irritation persists:

IF INHALED or symptoms of coughing, choking, or wheesing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Orlink promptly a targe quantity of water. Avoid alcohol. Get immediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agri-Bio Corporation, 966 Dorsey Street, Gamesville, Georgia 30501 U.S.A. EPA Reg. No. 778–91–63690. EPA Est. No. 62432-EN-001





Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter pyloridas Klebsiella pneumoniae Escherichia coli Salmonella typhimurium Salmonella typhimurium Salmonella tholeraesulis Pseudomonas aenuginosa Staphyloccoccus aureus Staphyloccoccus epidermidis Mycoptasma gallisepticum	Newcastle Disease infectious Bronchitis infectious Bursal Disease Autan Laryngotrachelitis Autan Influenza Marek's Disease	Aspergillus flavus Aspergillus flumigatus Candičia albicans

ACTIVE INGREDIENTS

Potassium peroxymonosulfate	111000011111111111111111111111111111111
Socilum Chindride	1 5%
WERT INGREDIENTS	
TOTAL	100.0%

Equivalent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN DANGER:

See Back Panel for Additional Precautions

11lbs (5kg) Net Weight

DISTRIBUTED BY



Agri-Bio Corp., a subsidiary of A.H. Robins Company, 966 Dorsey St, Galnesville, GA 30501, phone 1-800-AGRI-BIO

In Georgia call collect 404-536-0111

VIRKON S is a registered trademark of and manufactured by Antec International Limited U.S. Patent No: 4822512

Virkon, S

BROAD SPECTRUM DISINFECTANT

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotrachettis, Awan Influenza, and Marek's Disease.

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas seruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON \$ is recommended for use in hatcheries, chicken houses, and processing plants.

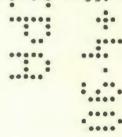
HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus flamqatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% for Mycoptasma, Aspergillus flavus, and Aspergillus fundingatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For dismlecting and deaning walls, ceilings, and floors spray at a dilution of 1%.

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.



Virkon, S

DILUTION CHART

FINAL SOLUTION	1% SOLUTION	2% SOLL/FION
American		2.7 punces
1 gation	1.3 aunces	1
10 galtons	13.4 punces	26.7 ounces
50 gallons	668 aunces	133.5 ounces
Metric		
10 Hers	100 grams	200 grams
50 liters	500 grams	1000 grams
200 liters	2 mgs	4 logs





The measure cap holds when fitted level 500g or 17.5 oursors.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL – Store in a cool, dry place in tightity closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective clothing and rubber gloves. Aword breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

IF IN EYES. Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention. IF ON SKIN. Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

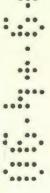
IF SWALLOWED, Drink promptly a large quantity of water. Avoid alcohol. Get minediate medical attention.

NOTICE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agn-Bro Corporation, 966 Dorsey Street, Galnesville, Georgia 30501 U.S.A. EPA Reg. No. 778–91–63690 EPA Est. No. 62432-EN-001









Virkon_®S

BROAD SPECTRUM DISINFECTANT

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST:

BACTERIA	VIRUSES OF	FUNGI
Streptococcus pyogenes Campylobacter byforidas (Idebsiella pneumoniae Escherichila coli Salmonella dholeraesuis Pseudomonas aeruginosa Staphylococcus auteus Saaphylococcus epidermidis Mycopiasma gallisepticum	Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease	Aspergillus flavus Aspergillus furnigatus Candida atbicaris

ACTIVE INGREDIENTS

Potassium peronymonosulfate	20	4%
Sodium Chloride		
MERT INGREDIENTS	78	195
TOTAL	100	.0%

Equivalent to 9.75% Available Chlorine

DANGER:

See Back Panel for Additional Precautions

11lbs (5kg) Net Weight

DISTRIBUTED O



Agri-Bio Corp., a subsidiary of A.H. Robins Company, 966 Dorsey St, Gainesville, GA 30501, phone 1-800-AGRI-BIO

In Georgia call collect 404-536-0111

VIRKON \$ is a registered trademark of and manufactured by Antec International Limited U.S. Patent No: 4822512

Virkon. S

BROAD SPECTRUM DISINFECTANT

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CONTROLS

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Lanyngotracheitis, Awan Influenza, and Marek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida albicans.

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimunum. Salmonella choteraesuis, Pseudomonas seruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum.

DIRECTIONS FOR USE

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VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers. humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes [use 2% for Mycoplasma, Aspergillus flavus, and

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S Juse 2% for Mycoplasma. Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or

emptoy equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, cellings, and floors spray at a dilution of 1%.

Virkon S is recommendeded for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Virkon S at 1-2% is suitable. Fog (wet mist) until the area is moist using automatic foggers according to manufacturer's use directions.

For air sanitizing: Virkon S at 1-2%; fog the atmosphere until surfaces are moist; allow at least 2 hours before entering area that has been fogged.

Virkon₈S

DILUTION CHART

QUANTITY OF FINAL SOLUTION	1% SOLUTION	2% SOLUTION
American		
1 gallon	1.3 ounces	2.7 ounces
10 gations	13.4 ounces	26.7 ounces
50 gations	66.8 ounces	133 S ounces
Metric		
1D litters	100 grams	200 grams
50 Atters	500 grams	1000 grams
200 liters	2 kas	4 focus





Brim full contains 200g or 7 nunces

The measure cap holds when filled level 500g or 175 ounces.

FOR DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

STORAGE AND DISPOSAL - store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals - DANGER, Corrosive. Causes skin burns and irreversible eye damage. Harmful If swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protective dothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated dothing and wash before reuse.

Practical Treatment

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention IF ON SIGN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

IF SWALLOWED: Drink promptly a large quantity of water. Avoid alcohol. Get Intimediate medical attention.

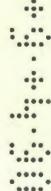
alcohol. Get Immediate medical attention.

NOTICE TO PHYSICIAN. Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for

Agri-Bro Corporation, 966 Dorsey Street, Galnesville, Georgia 30501 U.S.A. EPA Reg. No. 778-91-63690. EPA Est. No. 6243Z-EN-001





RECORD OF COMMUNICATION	DOTHER (SPECIFY)	
10.	(Record of item check	
Don Gilbert of A.H. Robins, (804)257-2035	Wallace Powell	DATE 8/23/90
SUBJECT VINKON S EPAR	eg. No. 778-91.	
WHMARY OF COMMUNICATION	L' - T : 11 / - /	011
. In response to his que (after I talked with Bill	Campbell):	ne tellowing
To send out a promot	tional flyer that says	the product
can be used for cleaning pour	y duranty (no danjuntos	+ de la
However, if the flyer is in	ichided with the product	auring
should apply for Amond	want to see the flyer	, and the
To send out a flyer	that sus the product	can be used
Go Send out a riger	is at hatchers for sette	ers implies
for fogging poultry building	would have to be appe	pued via
sanitization, so this use	in would be consider w	heather the
labeling amendment. The	with the and at ducin	ne shipping and
flyer would be included	with and he labelia	a) of the
sate (and so would be con	assaured to be investig	9) 01 100
(and would be considered	~	
I told him I'd FAX	him the standard co	mments shown
on the next page, to		•
		1000 (2)
(Note: Mr. Gilbert	mentioned a rebruar	y 1989 FUA.
letter that said it was c	skay to use the produ	ct for fogging
(Note: Mr. Gilbert letter that said it was a hatchiers and setters, with	the exception of table	e eggs.)

* Sanitization is the usual reason for fogging poultry buildings.

INFORMATION COPIES

TO:

- that "temporarily reduce the number of air-borne bacteria and viruses" or temporarily reduce the danger or hazard of air-borne infection."
- Togging applications of germicides and disinfectants cannot be accepted to disinfect air or room surfaces. Thus, such label representations as "germicidal fogging," "decontamination," and "disinfectant fogging" are not acceptable, and must be deleted.
- Consideration can be given to labeling bearing recommendations for fogging applications of chemicals to sanitize surfaces, provided that clear-cut directions are given limiting the application of such procedures to use as an adjunct to acceptable manual cleaning and disinfecting of room surfaces.

 Applications prior to manual cleaning and disinfecting
 - operations, or subsequent to such operations are considered as adjuncts to such operations. (The underlined wording, or very similar statements, must appear on the label text.)
- D-412 The terms "sterilize," "sterilizing," and "sterilization" denote the destruction of all living organisms. Since this product, used as directed, could not be relied upon to kill all living organisms including bacterial endospores, such claims are not justified and must be deleted. No objection would be raised to replacements such as "germicidal," "disinfect," or "bactericidal" providing, of course, that the product will provide such benefits.
- D-413 Drains which cannot be disassembled and manually cleaned cannot be disinfected. Therefore, claims made for such drain applications must be limited to deodorizing only.
- D-414 Hard water inactivation is largely a matter of slowing down the killing time and is only of major significance in those applications where speed of kill is essential, as in restaurants for dishes, glassware, and utensils. Since no such specific recommendations are made on the label where such action is vital, the hard water claim must be deleted.
- D-415 Delete all claims that the product is effective in disinfecting mattresses, upholstered furniture, pillows, or other
 textile materials unless data are submitted to support these
 claims. In lieu of this, the claims must be restricted to
 applications on hard, non-porous surfaces.

				Record	Number 262,
				Reference !	Number 4
				Inpu	t Date
CODING FORM FOR APPLIC	ATTIONS FOR E	REGISTRATIO	N/AMENDMENTS		
File Symbol/Reg. No.	778-91	PM 3	2 6 Act	ion Code 34	-6
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MAY 1 1 1990

Donald L. Gilbert
Director, Feed Additives
Research & Development and Regulatory Affairs
A.H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Subject: VirKon S

EPA Registration No. 778-91

Your Submission Dated March 21, 1990

Your Supplier's Submission (on Your Behalf)

Dated March 27, 1990

Dear Mr. Gilbert:

This is in response to submission of the Material Safety Data Sheet and chemical composition, requested in EPA letter dated March 8, 1990, for the ingredient

The information referred to above (and your amendment dated January 5, 1990, for addition of coloring agent), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Sincerely,

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H-7504C)

SURNAME | W. Pawell | DATE | Page 1320-1 (12-70) | Page 1320-1 (12

Inert ingredient information may be entitled to confidential treatment

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PRODUCT CHEMISTRY Review RSB

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	Product Name		Virkon S	
	Company Name	A. H. Robin's	Co., Inc.	
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MAY 1 1 1990

Donald L. Gilbert
Director, Feed Additives
Research & Development and Regulatory Affairs
A.H. Robins Company
1405 Cummings Drive
P.O. Box 26609
Richmond, VA 23261-6609

Subject: VirKon S

EPA Registration No. 778-91

Your Submission Dated March 21, 1990

Your Supplier's Submission (on Your Behalf)

Dated March 27, 1990

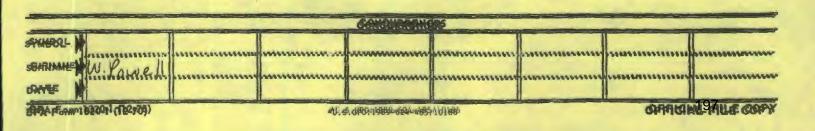
Dear Mr. Gilbert:

This is in response to submission of the Material Safety Data Sheet and chemical composition, requested in EPA letter dated March 8, 1990, for the ingredient

The information referred to above (and your amendment dated January 5, 1990, for addition of coloring agent), submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable.

Sincerely,

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (H-7504C)



Robert L. Miller, D.V.M.
Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco /TWX 7109560001
Telephone (804) XXXXXXX 257-2879

A-H-ROBINS

Mr. Walter C. Francis
Acting Product Manager (PM-32)
Document Processing Desk
Office of Pesticide Programs (H-7504C)
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

March 21, 1990

Re: EPA Reg. No. 778-91 VirKon S

Dear Mr. Francis:

Reference is made to your letter of March 8, 1990, requesting additional information on the fragrance in Virkon S.

The supplier, has supplied the enclosed Material Safety Data Sheet. The list of specific chemicals with CAS numbers will be supplied directly to the Agency by Because of their confidentiality requirements, they will not reveal this information to anyone except a regulatory agency.

Sincerely,

R. L. Miller, D.V.M.

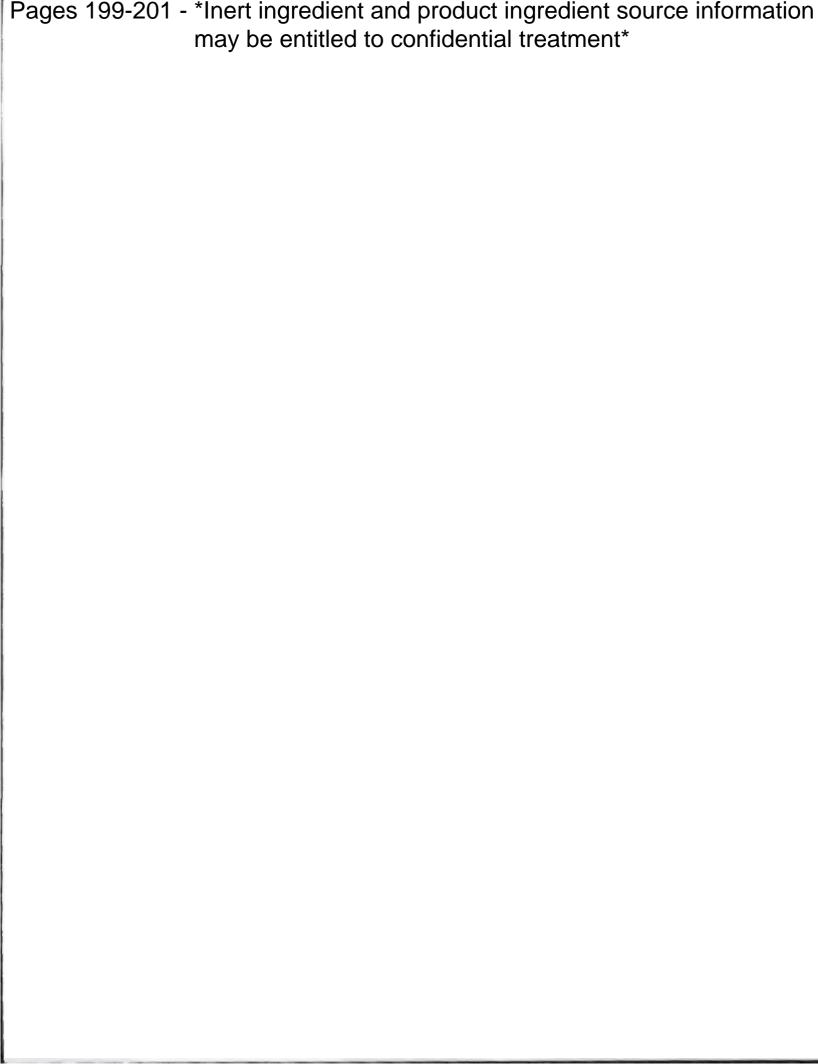
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Enclosure

RECEIVED

MAR 2 7 1990

ANTIMICROBIAL BRANCH



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MAR 0 8 1990

Robert L. Miller, D.V.M. A. H. Robins Company 1405 Cummings Drive P.O. Box 26609 Richmond, VA 23261-6609

Subject: Product Name: VirKon S

EPA Registration No.: 778-91

Your Amendment Dated January 5, 1990

Dear Dr. Miller:

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is not acceptable, for the reason given below.

For the perfume ask your supplier to submit to the Agency (a) a Material Safety Data Sheet, which should include Health Effects; and (b) chemical composition, which should include, for each chemical in the perfume mixture, the chemical name, the CAS Registry number, and the percentage or percentage range of the chemical in the perfume mixture.

Your Confirmatory Efficacy data and Confidential Statement of Formula are acceptable.

If you have any questions, you may call Wallace Powell at (703) 557-6938.

Sincerely,

Wood

Walter C. Francis Acting Product Manager (PM-32) Antimicriobial Program Branch Registration Division (H-7504C)

CONCURRENCES								
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Chemistry Review Product

	EPA Reg.	. No. or File Syn	abol	778-91	
	Daca Div	vision Received_		1-12-90	
	Products	Manager No		32 (France	is)
	Produce	Name		Virkon 5	
)t*	Company	Name A	. H. Robins C		
	100.0	Comments:			
eatr	a.	Addition	of dye,	7 T	is formulation
ial tre	2	would be	e acceptable	as en	is formication
enti	1	Homes	for to a la		perfume ask
confide	۵.	your Sug	slier to sulm	et to the	perfume ask and Material FS10 ots. For
		Complete	chemical co	mposition	FILL ots. For
d to		each co.	reponent in	perfume	mixture in chick
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1. Product Name 2. 3. 4. Action 5. MRID/ 6. Study Guideline or Narrative Record Number Code Accession Number Study Guideline or Narrative 7. Reference No. 8. Date Rec'd (EPA) 9. Prod/Review Mgr/DCI 10. PM/RM Team No. 11. Date to HED/ EFED/RD/BEAD 4-4-90 2 Anstructions	
2. 3. 4. Action 5. MRID/ 6. Study Guideline or Narrative Study Guideline o	
7. Reference No. 8. Date Rec'd (EPA) 9. Prod/Review Mgr/DCI 10. PM/RM Team No. 11. Date to HED/ EFED/RD/BEAD to Parructions	ate Returned RD/SRRD
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4 1-12-90 Francis 32 2-21-90 4-4-90 2	ate Returned RD/SRRD
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4 1-12-90 Francis 32 2-21-90 4-4-90 2	ate Returned RD/SRRD
4 1-12-90 Francis 32 2-21-90 4-4-90 2	ate Returned RD/SRRD
nstructions	120/90
instructions	
please review for addition of coloring agent	
Split review	
- print reviews	
This Section Applies to Review of Studies Only 14. Check Applicable Box 15. No. of Individual Studies	
14. Check Applicable Box Adverse 6(a)(2) Data (405) Generic Data (Reregistration)(660) 15. No. of Individual Studion Submitted	.es
Special Review Data (870) Product Specific Data (Reregistration) (655)	
16. Have any of the above studies (in whole or in part) been previously submitted for review?	
Yes (Please Identify the study(ies))	
18. To Type of Review 19. Reviews Also Sent to 20. Data Review C	riteria
Science Analysis & Coordination SAC PC A. Policy Note No. 31	
Toxicology/HFA TOX/HFA PL	
HED Toxicology/IR TOX/IR 1 = data which mee meet 3(c) (2) (B)	rt 6(a) (2) or
Dietary Exposure Nondietary Exposure DEB EA Criteria NDE AC	-599
Ecological Effects BA 2 = data of particular	ar concern
Environmental Fate & Groundwater EEB from registration	n standard
SPRD Reregistration SPRD Second Review	to detaria
SRRD Reregistration 3 = data necessary tiered testing re-	quirements
Insecticide-Rodenticide RER	
Fungicide-Herbicide GSC B. Section 18	
RD Antimicrobial 1 = data in support of in lieu of section	of section 3
Product Chemistry Precautionary Labeling	
Economic Analysis AM C. Inert Ingredients	
BEAD Analytical Chemistry 1 = data in support use of List 1 iner	of continued
Diological Analysis	
Confidential Statement of Formula (EPA Form 8570-4) Attached (Trade Secrets) Label Attached	

CONFIRMATORY DATA

EFFICACY EVALUTION AND TECHNICAL MANAGEMENT SECTION

Antimicrobial Program Branch

	In	01-12-90	Out	02-27-90	_	
EPA Reg. No.	or File	Symbol	778-91			
Product Name_			VIRKON	-S		
Company Name_		А. н.	Robins	Company, In	c.	
Submission Pur	rpose_	Confirmatory	Data fo	r change in	coloring agen	<u>t</u>
Date Applicat:	ion Red	ceived	02-21-	90		
Active Ingred	ients				8	
					20.4%	
Data Accession	n No. (or Identifica	tion No.	413821-01	_Product Manage	er No. <u>31</u>
Recommendation	ns:					
Confirmatory on the specime product as:				ort effi cac	y claims indication) the subject	
hos	spital	disinfectant				
X gen	neral (lisinfectant				
sal	nitize	for food co	ntact su	rfaces		
(1) The data	are a	cceptable	х			
(2) The data	are no	ot acceptable		See	explanation be	elow.
Labeling						
a. No adverse	comme	nts.				

Reviewed by Emily H. Mitchell

Date 02-27₂₀90

02/13/90

Product Name: VIRKON S
Company Name: A.H. ROBINS COMPANY
Application No.: 128563
EPA Reg. No.: 778-91
EPA Beceipt Date: 01/12/90

Subject: Front End Screen for an Amendment

Dear Sir or Madam:

Your application for registration has been received by the Office of Pesticide Programs and has passed a preliminary screen for completeness. It will be placed in line for review to determine its acceptability. The application will be processed in chronological order of receipt.

Although the 1988 FIFRA amendments mandate EPA to review applications for expedited registration or amendments within 90 days, this turnaround time will not be met immediately due to the backlog of applications received before pecember 24, 1988. However, EPA is increasing human and automated resources and making necessary procedural changes in order to eliminate the backlog and to meet the 90-day response time as soon as possible.

If you have any questions, you may contact Jeff Kempter, Product Manager 32 at (703)-557-3964.

Sincerely,

Team Leader

Lity Mener

Front End Processing Staff Registration Support Branch Registration Division (H7504C)

H75640 7 Which 2-13-90

Robert L. Miller, D.V.M. Vice President, Office of Veterinary Medicine

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 Cable Robinco /TWX 7109560001 Telephone (804) XXXXXXX 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

January 5, 1990

Re: VirKon S, 778-91

Dear Mr. Kempter:

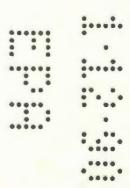
We wish to amend the original registration to provide for an alternate formulation containing a coloring agent.

Sincerely,

R. L. Miller, D.V.M.

dhe

Enclosures



3. Title

5. Date Signed

Vice President, Office of Veterinary Medicine

January 5, 1990

2. Signature

4. Typed Name

Paperwork Reduction Act Notice and Instructions

Paperwork Reduction Act Notice

Public reporting burden for this collection of Information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

- Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
- 2. Confidential Statement of Formula (EPA Form 8570-4).
- 3. Five copies of draft labeling.
- 4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on $8\ 1/2\ x\ 11$ inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an $8\ 1/2\ x\ 11$ inch file. Mockup labels significantly smaller than $8\ 1/2\ x\ 11$ inches should be mounted on $8\ 1/2\ x\ 11$ inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

- Company/Product Number Insert your company number, if one has been assigned. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
- 2. Dale : Fillan the appropriate date.
- 3. Product Manager 1 known, fill in the name and number of the Product Manager.
- 4. Proposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to shom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

 Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

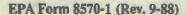
Section III - This Section must be completed for all applications submitted in connection with New Registration.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Specify the net contents of all retail containers for your product.
- Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- Manner in which label is affixed to product Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
- 6. EPA Use Only.



TRANSMITTAL DOCUMENT

Submitted

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609

Transmittal Date

January 5, 1990

Regulatory Action Supporting

Amendment, Addition of Coloring Agent EPA Reg. No. 778-91 Submitting in support of application

List of Submitted Studies

Prince, Daniel L., Ph.D. (1989), Lot Nos. 89/11/01, 89/11/02, EPA Amended Registration of VirKon-S Disinfectant AOAC Use Dilution Test, unpublished report prepared by Gibraltar Laboratories, Inc., Fairfield, NJ, 13 pp.

MRID #

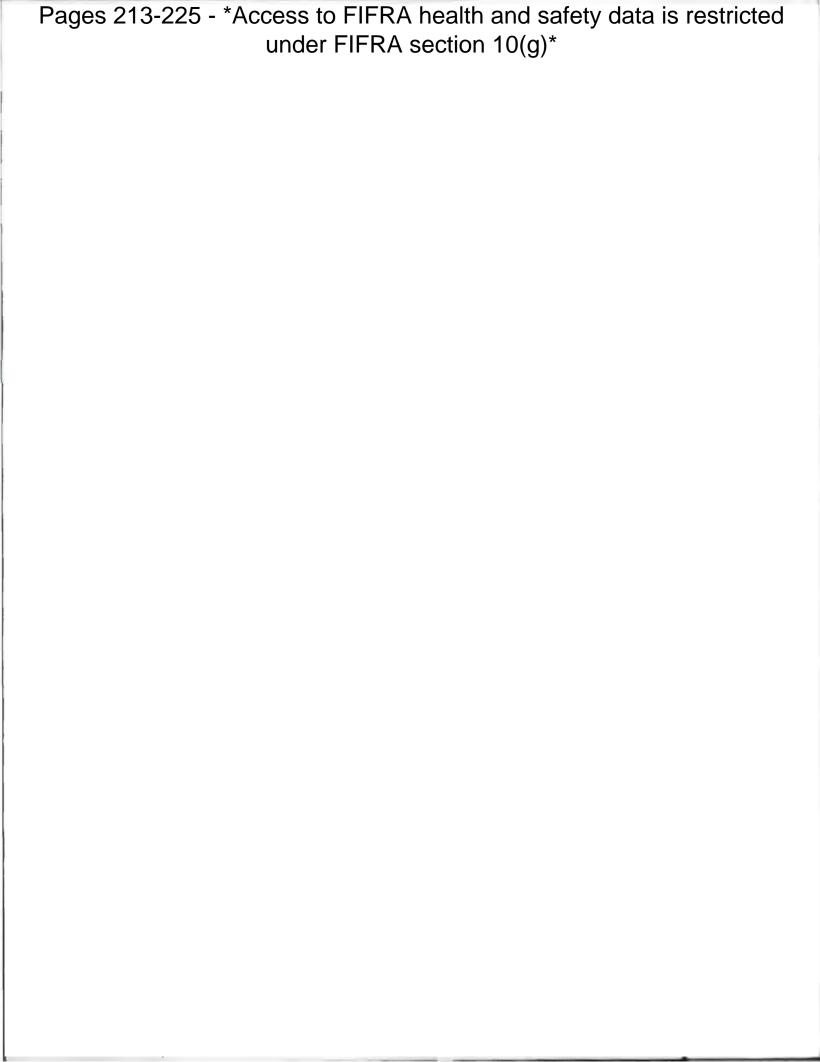
End of List

Transmitting Official

Robert L. Miller, D.V.M. Vice President, Office of Veterinary Medicine A. H. Robins Company

Robert Huller
(Signature)

(804) 257-2879' (Phone:



Robert L. Miller, D.V.M. Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Cummings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco /TWX 7109560001
Telephone (804) XXXXXXX 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

November 29, 1989

Re: VirKon S

EPA File Symbol 778-OR

Dear Mr. Kempter:

This letter will summarize our telephone conversation regarding requirements for adding a coloring agent and fragrance to VirKon S.

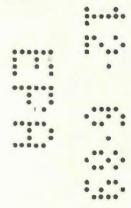
We will conduct antibacterial testing on two separate lots against Staphylococcus aureus and Salmonella choleraesuis. We will submit as an alternate formulation and include a revised Confidential Statement of Formula and refer to the original submission.

Sincerely,

Rh Wuller R. L. Miller, D.V.M.

dhe

c: Mr. D. L. Gilbert Dr. J. D. WNson



EPA REGISTRATION NO US ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) TERM OF ISSUANCE WASHINGTON, DC 20460 NAME OF PESTICIDE PRODUCT NOTICE OF PESTICIDE: HEGISTRATION REREGISTRATION (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended) NAME AND ADDRESS OF REGISTRANT (Include ZIP code) A.H. Bobins Company 1405 Cummings Drive P.O. Box 26609 Richmond, VA 23261-6609 NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product slways refer to the above U.S. EPA registration number. On the basis of information furnished by the registrant, the above named posticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered This product is conditionally registered in accordance with FIFPA sec. 3(c)(7)(A) provided that you. 1. Submit and/or cite all data required for registration/reregistration of your product under PIFRA sec. 3(c)(5) when the agency requires all registrants of similar products to submit such data. 2. Add the phrase "TPA Registration No. 778-91" to your labe! before you release the product for ahipment, 3. The accelerated storage and stability data at 37 °C for 29 days and for 6 months is acceptable on an interim basis. The results of 12 month stability test must be received by the Agency within 15 months after the granting of registration. 1. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 Enclosure for a further description of final printed labeling. S. Under Projectioner, Statements, and Danger, "before Corners."

EPA Form 8570-6 (Rev. 5-76)

ATTACHMENT IS APPLICABLE
SIGNATURE OF APPROVING OFFICIAL

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

58458:I/C:Pringle:K-5:KENCO:12/5/89:01/15/90:dg:sw:ek:dg

If these conditions are not complied with, the registration will be subject to cancellation in accordance with PIPRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Jeff Kempter

Product Manager (32)

Antimicrobial Program Branch Registration Division (H7505C)

Enclosures

VIRKON S Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial Animal and Agricultural Facilities

EFFECTIVE AGAINST --

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRSUSES OF:

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease

FUNGI:

Aspergillus flavus Aspergillus fumigatus Candida Albican

ACCEPTED
with COMMENTS
in EPA Letter Dated

DEC 8 1989

Under the Fotioral Insecticide.
Fungicida, and Rodenticide Act

Equivalent to 9.75% Available Chorine

KEEP OUT OF REACH OF CHILDREN

DANGER: See Back Panel for Additional Precautions

Net Weight 11 lbs (5.0 kg)

VIRKON S is a registered trademark of Antec International Limited
U. S. Patent Pending

BACK PANEL

VIRKON S Broad Spectrum Disinfectant

VIRKON S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Bursal Disease, Laryngotracheitis, Avian Influenza, and Marek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Salmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistent with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and water troughs, remove manure and litter and spray floors and side walls with VIRKON S at 1%. Thoroughly wash waterers and feeders with a 1% solution of VIRKON S (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

0	DILUTION CHART	
Quantity of		****
Final Solution	1%	2%
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 burices
50 gallons	66.8 ounces	133.5 ounces

For DISINFECTING use a rate of 7.5 gallons/1000 sq. ft. for CLEANING AND DISINFECTING use a rate of 15 gallons/1000 sq. ft.

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Hazards To Humans and Domestic Animals - Corrosive. Causes skin burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get prompt medical attention.

If on skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

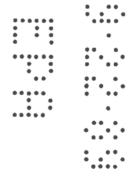
If inhaled or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

If swallowed: Drink promptly a large quantity of water. Avoid alcohol.

Notice to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for Agri-Bio Corporation 966 Dorsey Street Gainesville, Georgia 30501 U.S.A. EPA Reg. No. 778-____

EPA Est. No.



EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - I

Antimicrobial Program Branch

OUT 10-27-89

IN 10-10-89

a in al minus Delife
Reviewed By Emily H. Mitchell Date 10-27-89
EPA Reg. No. or File Symbol 778-OR
EPA Petition or EUP No. None
Date Division Received 10-23-89
Type Product(s) General Disinfectant
Data Accession No.(s) ARID 412-59-701
Product Mgr. No. PM 32 (Kempter)
Product Name(s) VIRKON-S
Company Name(s) A. H. Robins Company, Inc.
Submission Purpose Resubmission with additional data/information &
proposed label
Chemical & Formulation Powder
Active Ingredient(s):
Potassium peroxymonosulfate

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol	778-OR
Date Division Received	10-23-89
Data Accession No.(s)	
Product Manager No.	PM 32 (Kempter)
Product Name	VIRKON-S
Company Name A	. H. Robins Company, Inc.

- 202.0 Recommendations
- 202.1 Efficacy Supported by the Data:

 The data/information submitted clarifies the previous report.
- 203.0 <u>Labeling</u>

 No adverse comments.

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 10/10/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRID 41259701

Studies must be continuously paginated from the title page through the end of the study and all appendices—except for the Confidential Attachment or Supplemental Statement of Confidentiality Claims, if present—even when the study is large enough to span more than one physical volume.

Each of the independent study reports in this group should have been bound as a separate study.

Data Requirement Listings, Data Call-In Coversheets, EPA form 8570-1, EPA form 8570-4 and labels are considered to be administrative material rather than data and should not be bound as part of a study.

Robert L. Miller, D.V.M. Vice President, Office of Veterinary Medicine

A. H. Robins Company
1405 Curnings Drive
P. O. Box 26609
Richmond, Virginia 23261-6609
Cable Robinco / IVX 7 109560001
Jelephone (804) XXXXXXX 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

October 5, 1989

Re: VirKon S EPA File Symbol 778-OR

Dear Mr. Kempter:

Reference is made to your letter of September 28, 1989, regarding our supplemental submission of September 22, 1989.

The document rejected because of no title page or Statement of Data Confidentiality was not a report intended to stand on its own. It was an amendment to report number 48881, a part of the original submission. We are resubmitting the report containing the amendment. Since the original report contains a title page and Statement of Data Confidentiality, we believe we have satisfactorily responded to your questions. The report is presented in Attachment I (three copies).

Attachment II (five copies) is revised labeling that complies with your letter of August 28, 1989.

Sincerely,

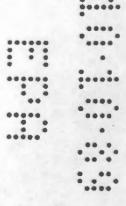
Roberthuil

R. L. Miller, D.V.M

dhc

Enclosures

ATTACHMENT I



TRANSMITTAL DOCUMENT

Submitter

Transmittal Date

A. H. Robins Company 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609 October 5, 1989

Regulatory Action Supporting

Registration, VirKon S EPA Reg. No. 778-OR

List of Submitted Studies

 Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of VirKon S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltar Biological Laboratories, Inc., Fairfield, NJ, 18 pp.

MRID # 41259761



file 778-0R SEP 28 1989

U. S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/22/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

The rejected documents below are identified with numbers which correlate to those taken from your submitted bibliography.

(01)

You must include one of the two acceptable statements of data confidentiality claims under FIFRA section 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

No title page was included for this study.

CARLTON J. KEMPTER PRODUCT MANAGER-32 DISINFECTANTS BRANCH

Robert L. Miller, D.V.M. Vice President, Office of Veterinary Medicine

A. H. Robins Company 1405 Cummings Drive P. O. Box 26009 Richmond, Virginia 23261-6609 Cable Robinco / IWX 7109560001 Jelephone (804) XXXXXXX 257-2879

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
Antimicrobial Products Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

September 18, 1989

Re: VirKon S EPA File Symbol 778-OR

Dear Mr. Kempter:

I refer to your letter of August 28, 1989, regarding our application for registration of VirKon S.

The enclosed revised labeling (Attachment I, five copies) addresses the deficiencies discussed in your letter. Attachment II (three copies) provides phenol resistance data.

I believe this submission addresses all deficiencies in the original application.

Sincerely,

R. L. Miller, D.V.M.

dhc

Enclosures

c: Dr. H. L. Easterbrooks

Mr. D. L. Gilbert

Mr. D. E. Jones

Mr. R. M. O'Hanlon

Dr. J. D. Wilson

Mr. Ralph Auchincloss (Antec)

ALIG 2 8 1989

A.H. Robbins Company, Inc. 1405 Cummings Drive P.O. Box 26609 Richmond, VA 23261-6609

Attention: H. Wayne Moran

Gentlemen:

Subject: Virkon S

EPA File Symbol 778-OR

Your Application Dated March 25, 1989

A review of your application for registration shows the following deficiencies.

Chemistry

According to your Confidential Statement of Formula (CSF) you may declare 20.4% Potassium peroxymonosulfate. Note that for the active ingredient the lower certified limit must be declared on the label.

If you intend to declare 22.5% Potassium peroxymonosulfate then submit revised CSF and revise certified limits for this ingredient.

Note the preferred declaration is: Potassium peroxymonosulfate.

Delete word Oxidant in front of Equivalent to 9.75% Available chlorine.

The net contents must be stated in terms of U.S. measure. There would then be no objection to an additional statement in terms of metric measure. It should be, Net Weight 110 lbs (50 kg). Enclosed product chemistry data is in compliance with 40 CFR Part 158.155 through 158.190 and is acceptable.

The accelerated storage and stability data at 37 °C for 25 days and for 6 months is acceptable on an interim basis. The results of 12 month stability test must be received by the Agency within 15 months after the granting of registration.

56958:I:Pringle:C.Disk:KENCO:K-4:08/24/89:10/06/89:de:JH:aw

CONCURRENCES					
SYMBOL					
SURNAME	***************************************				
DATE)					40
CDA Fam	1320-1 (12-70)				AL FILE COPY

Efficacy

- 1. Efficacy Supported by the Data:
 - a. The submitted data are acceptable to support effectiveness of the product, as a general disinfectant against all tested bacteria at a 1:100 dilution (1% in 400 ppm hard water) on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the tested bacteria. Refer to 2 below.
 - b. The submitted virucidal data are acceptable to support effectiveness of the product against Newcastle Disease Virus at a 1:100 dilution on hard, non-porous surfaces for a contact time of 10 minutes.
- 2. Additional Data/Information Required to Support Efficacy:
 - a. The phenol resistance must be provided for all tested bacteria.

O. Labeling

- a. On BACK PANEL change "Merek's Disease" to read "Marek's Disease".
- b. On BACK PAMEL change "Sallmonella choleraesuis" to read "Salmonella choleraesuis".

Acute Toxicity

RECOMMEND ATI ONS

The data submitted are adequate to place the product tested in the following toxicity category:

	STUDY	TOX CATEGORY
Sensitization-Negative	Acute Oral	111
	Acute Dermal	111
	Acute Inhalation	111
	Skin Irritation	1 undiluted - IV -5% dilution
	Eye Irritation	1 undiluted IV 5% dilution

CRP STATUS

This product does not require special packaging. Expand Hazard to Human and domestic Animals to read: Corrosive. Causes skin "burns" and irreversible eye damage.

The Statement of practical treatment has to be revised to read "Get prompt medical attention" after the recommended eye treatment.

Delete the words "milk, egg white, gelatin solution, or if these are not available," . . .

If you have any further questions please contact Ms. Barbara Pringle at 703-557-0484.

Sincerety yours,

Jeff Kempter Product Manager (32) Antimicrobial Program Branch

Registration Division (87505C)

VIRKON-S Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial Animal and Agricultral Facilities

EFFECTIVE AGAINST-

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF:

Newcastle Disease
Infectious Bronchitis
Infectious Bursal Disease
Avian Laryngotracheitis
Avian Influenza
Marek's Disease

FUNGI:

Aspergillus flavus Aspergillus fumigatus Candida Albican

Active Ingredients

Potassium monopersulfate	1.5%
Inert Ingredients	6.0%

Oxidant Equilavent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER: See Back Panel for Addition Precautions

Net Weight 5 kg

Virkon is a registered trademark of Antec International Limited U. S. Patent Pending.

BACK PANEL

VIRKON-S Broad Spectrum Disinfectant

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Brusal Disease, Laryngotracheitis, Avian Influenza, and Merek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Sallmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistant with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON_S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and feed water troughs, remove manure and litter and spray floors and side walls with VIRKON_S at 1%. Throughly wash waterers and feeders with a 1% solution of VIRKON_S. (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

0	DILUTION CHART	
Quanity of Final Solution	1%	2%
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces

For DISINFECTING use a rate of 7.5 gallons /1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons /1000 sq. ft.

BACK PANEL (cont'd)

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAUTIONARY STATEMENTS

Harzards To Humans and Domestic Animals - Corrosive. Causes burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and rubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with scap and water after hardling. Remove contaminated clothing and wash before rause.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

If an skin: Wash with plenty of scap and water. Get medical attention if irritation persists.

If inhaled or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

If sullowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for Agri-Bio Corporation 966 Dorsey Street Gainesville, Georgia 30501 U.S.A.

EPA Reg. No. 778-EPA Est. No.

Product Chemistry Review RSB

EPA Reg. No. or File Symbol	778-OR
Dace Division Received	4-7-89
Products Manager No.	32 (Kempter)
Product Name	IRKON S
Company Name A. H. Robins	Co., Inc.
2. According to your Co Formula you may deed peroxymonosulfate. Note ingredunt the lower of dictored on the laber If you intend to de peroxymonosulfate then stallment of tormula for this ingredient b. Note the preferred of peroxymonosulfate. c. Delik word Oxidant Available Chlorine. The net contents must additional statement additional statement of the sould be, Net e. Enclosed graduet compliance with the acceleration storage for 28 days and for an intermi basis stalility test must	clare 22.5% Potassium entificial limit must be submit revised Confiduation limits
Should Sodium c	bloride be declared as active
angreimen	ma Skapars 5-9-89 725 5/19/89 246

Title

Product Chemistry Data for VirKon-S and its Active Ingredients

Data Requirements

Guideline 158.120

Author

A. H. Robins Company

Study Completed On

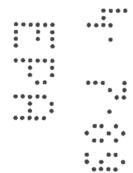
March 15, 1989

Performing Laboratory

A. H. Robins Company 1211 Sherwood Avenue Richmond, VA 23261-6609

Laboratory Project

Product Data for VirKon-S



Pages 248-278 - *Access to FIFRA health and safety data is restricted under FIFRA section 10(g)*

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - I

Antimicrobial Program Branch

OUT 08-21-89

IN 04-07-89

a in all chitaless.	
Reviewed By Emily H. Mitchell	Date 08-21-89
EPA Reg. No. or File Symbol 778	B-OR
EPA Petition or EUP No.	None
Date Division Received 04	-25-89
Type Product(s) General	l Disinfectant
Data Accession No.(s) 410574-10 &	410574-11 411083-01 & 411083-02
Product Mgr. No. PM	32 (Kempter)
Product Name(s) VI	RKON-S
Company Name(s) A. H. Robins	s Company, Inc.
Submission Purpose New submission w	ith efficacy data and proposed
label	
Chemical & Formulation	Powder
Active Ingredient(s):	-
Potassium monopersulfate Sodium Chloride	

200.0 Introduction

200.1 Uses:

A powder formula effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma.

200.2 Background Information:

The submission received 04-25-89, is a new submission with efficacy data and proposed label provided.

201.0 Data Summary (Accession Nos. 410574-10 & 410574-11 411083-01 & 411083-02)

201.2 Brief Description of Tests:

- a. Reports of Bactericidal Tests by Daniel L. Prince, Ph.D. Gibraltar Biological Laboratories, Inc. 122 Fairfield Road, Fairfield, New Jersey 07006
- Reports of Virucidal Tests by Daniel L. Prince, Ph.D. Gibraltar Biological Laboratories, Inc.
 122 Fairfield Road, Fairfield, New Jersey 07006

201.3 Test Summaries:

- a. Bactericidal Tests
 - 1. Method: A.O.A.C. Use Dilution Test, 14 Edition, 1984.
 - Modifications: 5% calf serum and 400 ppm
 A.O.A.C. hard water (CaCO₃)
 - 3. Samples:

Test Bacteria	Lot No.	Date Assayed	Date Completed
P. aeruginosa	08109160 02809160 03809160	1-16-89-1-19-89 1-23-89	1-26-89
S. aureus	08109106 02809160 03809160	1-16-89-1-19-89 1-23-89	1-26-89
S. choleraesuis	01809106 02809160 02809160	1-16-89-1-19-89 1-23-89	1-26-89

E. coli	01809160 02809160	01-27-89	02-16-89
S. pyogenes	01809160 02809160	01-27-89	02-16-89
S. typhi	01809160 02809160	01-27-89	02-16-89
K. pneumoniae	01809160 02809160	01-27-89	02-16-89
S. epidermidis	01809160 02809160	01-27-89	02-16-89
C. pyloridis	01809160 02809160	01-27-89	02-16-89
C. albicans	01809160 02809160	01-27-89	02-16-89

- 4. Dilution: 1% in 400 ppm
- 5. Exposure: 10 minutes at 20-25°C
- 6. Subculture Medium/Neutralizer: Letheen Broth
- 7. Incubation of Subcultures: 48 hours at 35+1°C
- 8. Test Bacteria:

Test Bacteria	Identification	Phenol Res.
Pseudomonas aeruginosa	15442 ATCC	Not Listed
Staphylococcus aureus	6538 ATCC	Not Listed
Salmonella choleraesuis	10708 ATCC	Not Listed
Streptococcus pyogenes	GBL #7	Not Listed
Salmonella typhi	GBL #106	Not Listed
Escherichia coli	GBL #642	Not Listed
Klebsiella pneumoniae	GBL #132	Not Listed
Staphylococcus epidermidis	GBL #6	Not Listed
Campylobacter pyloridis	GBL #775	Not Listed
Candida albicans	GBL #648	Not Listed

9. Survival of Inoculum on Control Carriers:

Test Bacteria	Average Colony Forming Units Per Carrier
P. aeruginosa	1.5 x 10 ⁶ 1.8 x 10 ⁶ 3.7 x 10 ⁵
S. aureus	$7.2 \times 10^4 1.3 \times 10^6 1.6 \times 10^5$
S. choleraesuis	$1.6 \times 10^5 4.2 \times 10^5 1.6 \times 10^5$
S. pyogenes	4.1 x 104
S. typhi	8.5 x 10 ⁵
E. coli	1.7 x 106
K. pneumoniae	2.9 x 106
S. epidermidis	9.3 x 10 ⁴
C. pyloridis	5.9 x 10 ⁵
C. albicans	3.7×10^4

10. Test Results:

Test Bacteria	Lot No.	No. Carriers Tested	No. of Carriers Demonstrating Growth
Pseudomonas aeruginosa	01809160 02809160 03809160	60 60 60	0 0 0
Staphylococcus aureus	01809106 02809160 03809160	60 60 60	0 0 0
Salmonella choleraesuis	01809106 02809160 03809160	60 60 60	0 0 0
Streptococcus pyogenes	01809160 02809160	10	0 0
Salmonella typhi	01809160 02809160	10 10	0 0
Escherichia coli	01809160 02809160	10	0 0 282

Klebsiella	01809160	10	0
pneumoniae	02809160	10	0
Staphylococcus	01809160	10	0
epidermidis	02809160	10	0
Campylobacter	01809160	10	0
pyloridis	02809160	10	0
Candida	01809160	10	0
albicans	02809160	10	0

11. Conclusions: Results show satisfactory performance of the product against all test bacteria when used at a 1% in 400 ppm dilution on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the bacteria tested.

c. Virucidal Tests

- 1. Method: EPA Test Method (DIS/TSS-7)
- Modifications: 10% fetal calf serum and hard water
- 3. Samples:

	Test
Date	Date
04-05-89	04-11-89
04-05-89	04-11-89
	04-05-89

- 4. Dilution: 1:100 (400 ppm A.O.A.C. H₂O) (1%)
- 5. Exposure: 20-25°C for 10 minutes
- 6. Recovery Medium/Neutralizer/Diluent: Trypticase Soy Broth with 10% calf serum
- 7. Incubation: 48 hours at 35°C
- Test Virus Host System:
 9-10 day old Chick Embryos

- 9. Drying Time and Temperature: 35°C for 30-45 minutes.
- 10. Assay System for Virus Recovery: Hemagglutination

ID-50 (-log 10)

- 11. Method For Estimating 50 per cent end point:
 Reed Muench Method
- 12. Test Virus: Newcastle Disease Virus
- 13. Test Results:

Test Virus	Batch No.	Virus Control	Virus Disin.	Toxicity Control	Virus Inacti- vation
Newcastle Disease	45616/1D 45616/2D	4.4	1.0	1.0	3.4 3.4

14. Conclusions: This product showed satisfactory performance against the test virus when used at a 1:100 dilution with 400 ppm A.O.A.C. water (1%) on hard, non-porous surfaces at a contact time of 10 minutes.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol _	778-OR
Date Division Received	04-25-89
Data Accession No.(s) 411083-	01 & 411083-02 410574-10 & 410574-11
Product Manager No.	PM 32 (Kempter)
Product Name	VIRKON-S
Company Name A.	H. Robins Company, Inc.

202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted data are acceptable to support effectiveness of the product, as a general disinfectant against all tested bacteria at a 1:100 dilution (1% in 400 ppm hard water) on hard non-porous surfaces for a contact time of 10 minutes. However, the phenol resistance must be provided for the tested bacteria. Refer to 202.2 below.
- b. The submitted virucidal data are acceptable to support effectiveness of the product against Newcastle Disease Virus at a 1:100 dilution on hard, non-porous surfaces for a contact time of 10 minutes.

202.2 Additional Data/Information Required to Support Efficacy:

a. The phenol resistance must be provided for all tested bacteria.

203.0 Labeling

- a. On BACK PANEL change "Merek's Disease" to read "Marek's Disease".
- b. On BACK PANEL change "Sallmonella choleraesuis" to read "Salmonella choleraesuis".

TECHNICAL SUPPORT SECTION TOXICOLOGY REVIEW - I

Disinfectants Branch May 19 89 May 19 89

	IN	OUT_		
Reviewed by	Alex Arce	. Date_	May 19 89	
	File Symbol_			
EPA Petition or	EUP No.			
Date Division R	eceived	4-25-89		
Type Product(s)	: I . D. H. F. N. R	, S		
Data Accession	No(s). 440574-02	to 09		
Product Mgr. No	. 32 Kampter			
Product Name(s)	VIRKON-6			
Company Name(s)	Agri- Bio Corp	oration		
Submission Purp	ose <u>Data label r</u>	eview - Regist	ration	
Chemical & Form	ulation liquid			
Active Ingredie	ent(s):		8_	
Potasium monope	rsulfate		22.5	
Sodium Chloride			1.5	

El Condor Form #1 3/88

BACKGROUND

The product will be used as a Disinfectant (Cleanin and Disinfecting animal and Agricultural RECOMMENDATIONS facilities)

The data submitted are adequate to place the product tested in the following toxicity category:

	STUDY	TOX CATEGORY
Sensitization-Negative	Acute Oral	111
	Acute Dermal	111
	Acute Inhalation	111
	Skin Irritation	l undiluted - 1V -5% dilution
	Eye Irritation	l undituted ly 5% dilution
	CED CED	10

CRP STATUS

m This product 3000 /does not require special packaging

Expand Hazard to Human and domestic Aminals to read: Corrosive. Causes skin"burns and irrabersible eye damage

The Statement of practical treatment has to be revised to read "Get prompt medical attention" after the recommended eye treatment.

Delete the word " milk ".

DATA REVIEW

	DAIA REVIEW	
Test Laboratory:	Biosearch Incorporated	
# 88-6437A		
	Acute Oral LD50 CFR 81.1	
Report date: 01	L-24-89 MRID No. 410574-02	
Method of Testing:	CFR 81-1	
Species: Rate		
Sex: Male and Fem	Levels Tested: 0.5,1.00,1.50,1.	78
Age: Adults	No. Animals/dose: 5 m and 5 f	0 g/kg
Weights: Acceptab	ble Via: Gavage	-
Material: Un dilute	ed Observation days: 14	
	Necropsy:all	
Procedure		
The r	rats were treated with the material by gavage and obs	er-
and for signs of t	toxicity , changes in body weight and other meaning -	zafa
ved for signs of		
ful parameters.		
ful parameters. Results:	Lethargy, ruffled hair	
ful parameters. Results: Signs of Toxicity: Body Weights: Unrer	markable	
ful parameters. Results: Signs of Toxicity: Body Weights: Unrer Mortality: -all at	markable 2.00 and 2.50 g/kg , 2, at 1.78 (males) 4 at 1.50	and :
ful parameters. Results: Signs of Toxicity: Body Weights: Unrer Mortality: -all at	markable 2.00 and 2.50 g/kg , 2, at 1.78 (males) 4 at 1.50	and :
ful parameters. Results: Signs of Toxicity: Body Weights: Unrer Mortality: -all at Necropsy: Irritation	markable 2.00 and 2.50 g/kg , 2, at 1.78 (males) 4 at 1.50 on of lungs and G. I tract at 1.6	and :
ful parameters. Results: Signs of Toxicity: Body Weights: Unrer Mortality: -all at Necropsy: Irritation	markable 2.00 and 2.50 g/kg , 2, at 1.78 (males) 4 at 1.50	

Acute Dermal LDsn CFR 81.2

Project	88-643/A

Report Date: 12-28-88	MRID No. 410574-03
Method of Testing: CFR 81-2	
Species: rabbits	Levels Tested 2.0 g/kg
Sex: male and female	No./animals/dose 5m and 5 f
Age: Adults	Via: Occluded patch
Weight: Acceptable	Observation days: 14
Material: Undiluted	Necropsy: All
Procedure	
The animals were treated with the amte	rial in previously clipped areas
of the skin in the back , and observed	for signs of toxicity and chan
ges in body weights	
Result	
Signs of Toxicity: Dermal irritation	DIO
Mortality:	
Body weights: Unwarkable	
Necropsy: Unremarkable	
Conclusions: The Acute Dermal LD50 is	greated than 2.0 g/kg
Core	data
Toxicity Category: 111	

Acute Inhalation LC50

CFR 81.3

Report Date: 12-19-88	RID: 410574-04
Method of Testing: CFR 81-3	
Species: rabbits	Levels tested: 4.86 w/w
Sex: male and female	No.animals/dose: 5 and 5
Age: _adulte	Via: Inhalation chamber
Weight: Acceptable	Observation days:
Material: in deignized water	Necropsy: all
Procedure	
namber for 242 minutes. Measurements onitored and the animals were observe ehavior. Results	
Signs of toxicity: Unremarkable	
Mortality: None	
Body Weightsenremarkable	
Necropsy: No gros pathology	
Conclusions: The Acute Inhalation LCs	50 is 6.147 mg/l combined
Coredata	
Toxicity Category: 111	

The procedures were similar	port is for the undiluted materia-
Report Date: 12 13 98	MRID No.: 410574-07 and -08
Method of Testing: CPD 81-5	
Species: Robbits	Observation days: 14 days
No. of animals 6	Material: Undiluted and 5 %
0.5 ml	Via:Occluded patch
Areas: In the back	Necropsy: No
Procedure The animals were tr	reated with the material in previously
clipped areas of the back and	observed for signs of toxicity -

Conclusion: The product is a Severe skin irritant

data

The 5 % solution fail; ed to induce irritation

Core Minimum

Toxicity Category:___

	-4-	
Primary Eye Irritation	CFR 81.4	
his is a review of the undilu	ted material test. (ther test using
% solution failed to induce :	irritation. Both tes	st were performed follo -
ing the same method Report Date: 11-15-88	MRID No.:_	410574-05and 06
Method of Testing CFR 8		
Species: Rabbits	Observat	ion days: 2
Dose: 0.1 ml		
No. of animals: 6		e instillation
Areas: In one eye	Necrops	None None
The animals were one eye , other served as continued		terial instilled in or occular damage
Results: 6/6 Corne	al canadas 6/6	
0/0	at obacity ove	Iritis developed
Conjunctival irritation was		Iritis developed

The 5 % dilution failed to induce severe or other damge

Core Minimum data

Toxicity Category: 1 - Corrosive

Dermal Sensitization

CFR. 81.6

Report Date: 01-26-89	MRID No. 41-05-74
Method of Testing:CFR 81-6	
Specie:	Observation days: after challenge Challenge application day: 2 weeks aft Via: occluded patch
Material:	- · · · · · · · · · · · · · · · · · · ·
PROCEDURE The animals were treated with the mareas of the back for two weeks, a two other weeks a challenge dose was were performed.	
Results:	
Erythema: None Edema: None	
Conclusions: The product is not	dermal sensitizer
Core Minimum data Toxicity Category: N/a	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

Product Name: VIRKON-S	PESTICIDES AND TOXIC SUBSTANC
EPA File Symbol: 778-0R	Ann
Application Date: 3-25-89	APR 1 9 1989
Receipt Date: 4-7-89	
Dear Registrant:	
A cursory review of your application incomplete. Please provide the item(s) be or your application will be administrative Refer to the Code of Federal Regulations, to 180 for a full description of all requiany questions, you may contact	low within 75 days ly withdrawn. Title 40, parts 152 rements. If you have at 703-557-0484. A for 8570-4 enclosed). osed). n of Data (EPA form ed per P.R. Notice 86-5:
	mpter Manager 32
	robial Program Branch ation Division (TS-767C)

VIRKON-S Broad Spectrum Disinfectant

For Use in Cleaning and Disinfecting Industrial Animal and Agricultral Facilities

EFFECTIVE AGAINST-

BACTERIA:

Streptococcus pyogenes
Campylobacter pyloridas
Klebsiella pneumoniae
Escherichia coli
Salmonella typhimurium
Salmonella choleraesuis
Pseudomonas aeruginosa
Staphylococcus aureus
Staphylococcus epidermidis
Mycoplasma gallisepticum

VIRUSES OF:

Newcastle Disease Infectious Bronchitis Infectious Bursal Disease Avian Laryngotracheitis Avian Influenza Marek's Disease

FUNGI:

Aspergillus flavus Aspergillus fumigatus Candida Albican

Active Ingredients	
Potassium monopersulfate	22.5%
Sodium Chloride	1.5%
Inert Ingredients	

100.0%

Oxidant Equilavent to 9.75% Available Chlorine

KEEP OUT OF REACH OF CHILDREN

DANGER: See Back Panel for Addition Precautions

Net Weight 5 kg

Virkon is a registered trademark of Antec International Limited U. S. Patent Pending.

BACK PANEL

VIRKON-S Broad Spectrum Disinfectant

VIRKON-S is effective against numerous microorganisms affecting animals: viruses, gram positive and gram negative bacteria, fungi (molds and yeasts), and mycoplasma. Efficacy was determined in the presence of hard water and organic material.

Controls:

Viruses of - Newcastle Disease, Infectious Bronchitis, Infectious Brusal Disease, Laryngotracheitis, Avian Influenza, and Merek's Disease

Fungi (molds and yeasts) - Aspergillus flavus, Aspergillus fumigatus, and Candida Albicans

Bacteria - Streptococcus pyogenes, Campylobacter pyloridas, Klebsiella pneumoniae, Escherichia coli, Salmonella typhimurium, Sallmonella choleraesuis, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis, Mycoplasma gallisepticum

DIRECTIONS FOR USE

Federal law prohibits use of this product in a manner inconsistant with its labeling.

This powder formula is easily diluted for use in manual or machine operations.

VIRKON_S is recommended for use in hatcheries, chicken houses, and processing plants.

HATCHERIES: VIRKON_S at 1% is generally suitable for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, ceiling fans, chicken houses, transfer trucks, trays, and plastic chick boxes (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus).

BROILER/BREEDER HOUSES: Following removal of chickens, feed, and feed water troughs, remove manure and litter and spray floors and side walls with VIRKON_S at 1%. Throughly wash waterers and feeders with a 1% solution of VIRKON_S. (use 2% for Mycoplasma, Aspergillus flavus, and Aspergillus fumigatus). After contact for 10 minutes, rinse with potable water. Do not use to house poultry or employ equipment until treatment has dried.

PROCESSING PLANTS: For disinfecting and cleaning walls, ceilings, and floors spray at a dilution of 1%.

Cuppity of	DILUTION CHART	
Quanity of Final Solution	1%	2%
1 gallon	1.3 ounces	2.7 ounces
10 gallons	13.4 ounces	26.7 ounces
50 gallons	66.8 ounces	133.5 ounces

For DISINFECTING use a rate of 7.5 gallons /1000 sq. ft. For CLEANING AND DISINFECTING use a rate of 15 gallons /1000 sq. ft.

BACK PANEL (cont'd)

Storage and Disposal - Store in a cool, dry place in tightly closed container. Always replace lid after use. Wash empty container thoroughly and dispose of in trash.

PRECAULIONARY STATEMENTS

Harzards To Humans and Durestic Animals - Corrosive. Causes burns and irreversible eye damage. Harmful if swallowed, absorbed through skin, or inhaled. Do not get in eyes, on skin, or on clothing. Wear protecting clothing and nubber gloves. Avoid breathing dust. Wear goggles, face shield, or safety glasses. Wash thoroughly with scap and water after handling. Remove contaminated clothing and wash before reuse.

Practical Treatment

If in eyes: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

If on skin: Wash with plenty of scep and water. Get medical attention if irritation persists.

If irrialed or symptoms of coughing, choking, or wheezing are troublesome, remove to fresh air and seek medical attention.

If sallowed: Drink promptly a large quantity of milk, egg white, gelatin solution, or, if these are not available, large quantities of water. Avoid alcohol.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Manufactured for Agri-Bio Corporation 966 Dorsey Street Gainesville, Georgia 30501 U.S.A. EPA Reg. No. 778_____EPA Est. No.

U. S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

A.H. ROBINS CO. INC.
P. O. BOX 26609
1405 CUMMINGS DR.
RICHMOND, VA 23261

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 04/07/89. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRID 41057401

The Good Laboratory Practice Statement should appear on page 3 of the study. See page 17 of PR Notice 86-5.

The statement of data confidentiality claims must appear on page 2 of each study. See pages 6 and 17 of PR Notice 86-5.

A. H. Robins Compar's 1407 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 Cable Robinco/TWX 1109560001 Telephone (804) 257-2000

A-H-ROBINS

Mr. Jeff Kempter Product Manager (32) U.S. ENVIRONMENTAL PROTECTION AGENCY Insecticide-Rodenticide Branch 1921 Jefferson Davis Hwy. Arlington, VA 22202

March 30, 1989

RE: Submission of Application for Registration of New Product VirKon-SR

Dear Mr. Edwards:

The A. H. Robins Company is submitting application for registration of the above named product. In accordance with applicable regulations, the following documentation is enclosed fulfilling the informational requirements for such registration.

- 1) EPA Form 8570-1; Application for Registration
- 2) Five (5) copies of proposed labeling
- 3) List of Registration Data Requirements
- 4) EPA Form 8570-28; Certification with Respect to Citation of Data
- 5) EPA Form 8570-4; Confidential Statement of Formula
- 6) Required Data: Product Chemistry, Acute Toxicology, Efficacy

Studies of the product's effectiveness against several of the claimed microbes have not been submitted. Submission was understood to be unnecessary as the agents were considered to not be human pathogens (statement enclosed).

For your information, we have also included a section from the manufacturers manual explaining the chemistry and possible method of action for the product.

Respectfully Submitted,

H. Wayne Moran

Manager, Regulatory Affairs

Wayne M/sa

Pet Care Products R&D

Office of Veterinary Medicine

wmc

TRANSMITTAL DOCUMENT

Submitter

Transmittal Date

A. H. Robins Co. 1405 Cummings Drive Richmond, VA 23261-6609 March 30, 1989

Regulatory Action Supporting

Registration, VirKon-S EPA Reg. No. 778-OE

List of Submitted Studies

1. Product Chemistry Data for VirKon-S and its active ingredients. Unpublished report submitted by A. H. Robins Co., Richmond, VA

MRTD#_ 41057401_

2. Gabriel, David - (1988) A. H. Robins Disinfectant, Lot No. 02809160, Acute Oral Toxicity, LD50, AHR 88-197, unpublished report prepared by Biosearch, Inc., Philadelphia, PA, 19 pp.

MRID# 41057402

3. Gabriel, David - (1988) A. H. Robins Disinfectant, Lot No. 02809160, Acute Dermal Toxicity, LD50, AHR 88-199, unpublished report prepared by Biosearch, Inc., Philadelphia, PA, 8 pp.

MRID# 41057403

4. Hershman, Richard J. ~ (1988) VirKon-S, A. H. Robins Disinfectant, Lot No. 02809160, Acute Inhalation Toxicity, Single Level, AHR 88-198, unpublished report by Biosearch, Philadelphia, PA, 21 pp.

MRID# 41057404

5. Moore, George E. (1988) VirKon-S, A. H. Robins Disinfectant (Supplied), Lot No. 02809160, Primary Eye Irritation, AHR 88-195, unpublished report by Biosearch, Inc., Philadelphia, PA, 11 pp.

MRID# 41057405

301

TRANSMITTAL DOCUMENT (cont'd)

6. Moore, George E. - (1989) VirKon-S, A. H. Robins Disinfectant (5% Dilution), Lot No. 02809160, Primary Eye Irritation, AHR 88-195, unpublished report by Biosearch, Inc., Philadelphia, PA, 11 pp.

MRID# 41057406

7. Gabriel, David - (1989) VirKon-S, A. H. Robins Disinfectant (Supplied), Lot No. 02809160, Primary Skin Irritation, AHR 88-194, unpublished report by Biosearch, Inc., Philadelphia, PA, 9 pp.

MRID# 41057407

8. Gabriel, David - (1989) VirKon-S, A. H. Robins Disinfectant (5% Dilution), Lot No. 02809160, Primary Skin Irritation, AHR 88-194, unpublished report by Biosearch, Inc., Philadelphia, PA, 8 pp.

MRID# 41057408

9. Daniels, Donna S. - (1989) VirKon-S, A. H. Robins Disinfectant, Lot No. 02809160, Guinea Pig Dermal Sensitization - Modified Buehler Method, AHR 88-196, unpublished report by Biosearch, Inc., Philadelphia, PA, 16 pp.

MRID# 41057409

10. Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of Virkon-S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltor Biological Laboratories, Inc., Fairfield, NJ, 18 pp.

MRID# .. 41057410

11. Prince, Daniel L., Ph.D. - (1989) EPA Primary Registration of Wirkon-S Disinfectant, AOAC Use Dilution Test, unpublished report prepared by Gibraltor Biological Laboratories, Inc., Fairfield, NJ, 15 pp.

MRID# 41057411

End of List

TRANSMITTAL DOCUMENT (cont'd)

Transmittal Official

H. Wayne Moran Manager, Regulatory Atlairs, Pet Care Products R&D, Office of Veterinary Medicine, A. H. Robins Co.

Signature

804-257-2049 Phone

VIRKON S

CHEMICAL REACTIONS - PRODUCT CLASSIFICATION



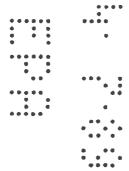


- ⇒ Appendix II
- * Photocopies attached.

T R Auchincloss, BSc, C Chem, FRSC Chairman

noth Class

TRA/SAM/17.7.87/S184



A. H. Robins Company 1407 Cummings Drive P. O. Box 26609 Richmond, Virginia 23261-6609 Cable Robinco/TWX 7109560001 Telephone (804) 257-2000

A-H-ROBINS

Mr. Jeff Kempter
Product Manager (32)
U.S. ENVIRONMENTAL PROTECTION
AGENCY
Insecticide-Rodenticide Branch
1921 Jefferson Davis Hwy.
Arlington, VA 22202

March 30, 1989

RE: Submission of Application for Registration of New Product VirKon-SR

Dear Mr. Edwards:

The A. H. Robins Company is submitting application for registration of the above named product. In accordance with applicable regulations, the following documentation is enclosed fulfilling the informational requirements for such registration.

1) EPA Form 8570-1; Application for Registration

2) Five (5) copies of proposed labeling3) List of Registration Data Requirements

4) EPA Form 8570-28; Certification with Respect to Citation of Data

5) EPA Form 8570-4; Confidential Statement of Formula

6) Required Data: Product Chemistry, Acute Toxicology, Efficacy

Studies of the product's effectiveness against several of the claimed microbes have not been submitted. Submission was understood to be unnecessary as the agents were considered to not be human pathogens (statement enclosed).

For your information, we have also included a section from the manufacturers manual explaining the chemistry and possible method of action for the product.

Respectfully Submitted,

H. Wayne Moran

Manager, Regulatory Affairs

Wayne Mora

Pet Care Products R&D

Office of Veterinary Medicine

wmc

BE. THE HALOGENS

Turning to the Food Industry, the B.D.M.A. is currently working to develop an approval schedule on the lines of that used in the Milk and Dairies Industry. The Chief Medical Officer of the Ministry of Health, reporting 'on the State of the public health in England and Wales for the year 1967', includes a section on the use of detergents and sterilants in food premises. This states that 'chlorine and hypochlorites are among the best sterilants available for the food industry provided they are properly used . . .'. (p. 153).

When the first men to set foot on the moon returned to earth at the successful conclusion of the Apollo 11 mission (24-7-69), an iodophor and a hypochlorite solution were chosen as two of the disinfectants for use in the decontamination process to kill possible agents of infection which might have been brought back from the moon.

B. CHEMICAL REACTIVITY

The common halogens as a group, comprising fluorine, chlorine, bromine and iodine are characterized by their extreme reactivity which is generally of an oxidizing nature. Fluorine is one of the most reactive of all the elements, and is much too reactive in terms of toxicity, irritancy and corrosiveness to be used in any disinfectant applications.

Active bromine compounds are normally also too toxic and irritant for wide use, although there are some bromine compounds which have applications in halogen mixtures (p. 164). The rapid germicidal power of the halogens is undoubtedly due to the high oxidizing reactivity by which the activity of all cellular proteins is destroyed. The active entity is either the free halogen or hypohalous acid. These two form an equilibrium which is dependent on pH.

$$X_2 + HOH \rightleftharpoons HOX \rightleftharpoons OX^- ; HOH $+ H^+X^-$ (1)$$

(where X is a halogen atom)

lodine when used as a disinfectant in iodophors (p. 174) is normally present under acid conditions, and it is the free iodine which is active (loosely complexed with nonionic surface active agents). In the case of chlorine, the solution would be unstable under acid conditions and chlorine gas would be liberated. For this reason liquid hypochlorites are normally formulated on the alkaline side of neutrality.

$$Cl_2 + HOH \rightleftharpoons HOCl \xrightarrow{\text{OH}^+} OCl + - HOH$$

$$\downarrow HCl \qquad Cl^+$$

$$(2)$$

It is generally agreed (Sykes, 1955), that undissociated hypochlorous acid, HOCl, is the important germicidally active species, and this is in line with the improvement in germicidal activity with reduced pH (p. 150).

Referring to the equilibrium depicted in equation 2, Allen (1950) quoted figures sliving 99-7% undesociated HOCl at pH 5, 73% at pH 7, and only 0-3% at pH 50. At pH values below 5, the equilibrium becomes unstable due to the formation of Cl₂, while at higher pH values the concentration of OCl-jons becomes appreciable. Although it is clear that alkaline solutions of sodium hypochlorite even at pH's above 10 are germicidal (see Tables P and PV), it is not yet certain what contribution the OCl-jon makes. In practice this matters little because the dynamic equilibrium ensures that FIOCl is continually replaced as it is used up.

These basic mechanisms are most easily represented in the case of solutions of sodium hypochlorite, but they also apply to a range of organic N-chloro compounds (p. 162) which have been developed in recent years, and which are germicidal in solution, hydrolysing in varying degree to HOCl. There are also several examples of improved activity in halogen mixtures in which hypobromous acid and hypoiodous acid play a part; this is thought to be due to the lower degree of ionization of these two hypohalous acids, leading to more of the germicidally active entity. Further, it has been found that N-halogen organic compounds containing both bromine and chlorine may be superior to those containing only bromine or chlorine (Paterson, 1965, Table XIV).

Hypochlorous acid will liberate iodine from potassium iodide solution and titration of the iodine so liberated with sodium thiosulphate affords a rapid method for determining strengths of hypochlorite solutions (p. 144).

Halogen disinfectants tend to decompose to varying extents, on prolonged storage, the extent depending on the storage conditions.

C. HALOGENS AS STERILIZING AGENTS

Compounds in this class form one of the few groups of disinfectants which can be called sterilizing agents in the strict sense that they will kill the complete spectrum of microorganisms. The reason for this is that all forms of microorganism depend on protein both enzymatic and structural for continued life and that the halogens will oxidize and react readily, rapidly and destructively with proteins. The nucleic acids are also potential targets for the halogens. In general, vegetative cells are killed rapidly. Knox et al. (1948) have produced evidence to suggest that enzymes containing SH groups are especially sensitive targets for chlorine in the bacterial cell.

Bringham (1953) studied electron micrographs of bacteria treated

Accelerated Oxidation

Some occuliar effects in the bleaching of coloured goods have been investigated between 1930 and 1940 with very interesting results. It is common experience with many textile technologists that some of the yellow vat dveings on cotton and rayon produced tendering when exposed to light under conditions which were without effect on the undyed material. Scholefield and Patel (LS.D.C., 1929, 45, 175) found that with dyed material—certain vat yellows and oranges --treatment with hypochlorite in presence of light brought about tendering which did not occur in the dark. Derrett-Smith and Nodder (J.T.I., 1932, 23, 293) investigated the action of hypochlorite solutions over a wide range of pH values, on cotton dyed with certain vat and azoic dyes; yellow, orange and red dyes were active and tendered the cellulose, the greatest effect taking place in the neutral region. It was suggested by Scholefield and Turner (ibid., 1033, 21, 3301) that in presence of light, these active dyes can be reduced to their leuco forms, which, during exidation (by air or other oxidising agent) bring about a strong simultaneous oxidation of the cellulose. Oxidations of this type are known to occur with a variety of organic compounds (Traube, Ber., 1881, 15, 659, 2421, 2434; 1883, 16, 123; Engles et al., see Chem. Soc. Ann. Rep., 1024. p. 100).

Turner, Nabar and Scholefield (J.S.D.C., 1935, 51, 5) confirmed this activating effect of reduced vat dyes on cotton in hypochlorite solutions, and found that the effect depends to a large extent on the concentration of dye on the fibre. The increased rate of oxidation of cellulose in sodium hypochlorite solution at pH 7 in presence of leuco-vat dyes is so great that for the same fluidity a number of seconds is adequate in place of the hours required in absence of dye. In presence of a third substance which is oxidised, cellulose is not protected from oxidation but is attacked with increased vigour. The suggested addition of oxalic acid to hypochlorite solutions in 1877 (G.P. 21,8) certainly produced "a stronger bleaching effect" and mixtures of dichromate-oxalic acid have been used (Clibbens and Ridge, J.T.I., 1927, 18, 135) in recent times for the purpose of forming oxycellulose, which is produced much more rapidly than with dichromate-sulphuric acid.

Accelerated oxidation with hypochlorites has been examined in some detail by Kauffmann (Ber., 1932, 65, 179) who showed that the destruction of certain readily oxidisable dyes by hypochlorite is increased by the addition of small proportions of hydrogen peroxide. It was also established that cellulose itself was attacked by the accelerated oxidation of the activated hypochlorite; other agents capable of acting as activators are ammonia, chloramine, acid amides

and amino-acids. This is a departure from the usual opinion that hypochlorous acid is the agent which is responsible for attack on the fibre during uncontrolled bleaching, and is formed according to the scheme

Actually, Kauffmann found that there was only slight attack on cellulose by hypochlorous acid, alone,

A number of dyestulis are readily bleached by dilute sodium hypochlorite solution but the bleaching action is slower in presence of NaO11; the addition of hydrogen pervaide to hypochlorite solution produces rapid bleaching, but with ammonia there is a certain period of induction during which chloramine is formed, similarly with urea, when dichlorurea is formed. Chemical compounds of very different types can produce this effect, as for instance, dimethylglyoxime. The presence of these activators in hypochlorite bleach liquors may produce tendering of the cellulose.

Kauffmann is of the opinion that in bleaching, two substances are necessary, the oxidising agent and the activator; with hypochlorites the oxidising agent is the hypochlorite ion and the activator is hypochlorous acid which should not exceed about 1 mg. per litre. Bleach liquors containing higher proportions of activators are injurious to the cellulose.

This effect is interpreted on the basis of the Haber-Willstätter theory of chain-reactions, the activators being substances which form hydroxyl ions in solution. With hydrogen peroxide, for instance, the first stage is

$$II_2O_2 + ClO^- \longrightarrow IIO_3 + Cl^- + OII$$

followed by

or .

This generates hydroxyl ions:

$$CIO + CIO + OII - \rightarrow 2 Cl + O_2 + OII.$$

The process continues until the hydroxyl is used completely in the reaction

$$OH + IIO_2 \longrightarrow H_2O + O_2$$
.

With neither eatalyst nor activator, the following reaction occurs:

The decomposition of hypochlorite is a second order reaction and calculations show that maximum activity takes place at pH 7 to 8.

It will be seen, therefore, that a very considerable amount of theoretical and practical evidence is available on accelerated oxidation and activated bleach liquors, as a result of which the bleaching

A-H-ROBINS

date March 16, 1989

memo from Dr. Robert L. Miller

to Mr. H. Wayne Moran

SUBJECT: VirKon S Registration

The following listed bacteria, fungi, and viruses are not considered human pathogens:

Bacteria: Mycoplasma gallisepticum

Fungi: Aspergillus flavus
Aspergillus fumigatus

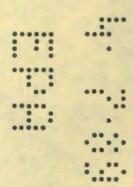
Viruses: Newcastle Disease Virus

Infectious Bronchitis Virus Infectious Bursal Virus Laryngotracheitis Virus Avian Influenza Virus Marek's Disease Virus

> Rh Willer R. L. Miller, D.V.M.

dhc

c: Dr. E. J. Corrigan



GENERAL INFORMATION

1. General Properties

VIRKON S - the most advanced virucidal disinfectant in the world - combining wide spectrum virucidal activity with excellent bactericidal and fungicidal properties.

Patents have been applied for in the USA and Japan. Initial patent granted in the UK. Patent improvements filed.

VIRKON S is unique in its composition. Its activity is based on a synergised acid peroxygen system containing a high percentage of surfactant. It can clean and sanitize in one operation.

VIRKON S is completely safe to use — non-tainting, non-corrosive, non-toxic, free from residue problems as the biocidal system is totally inorganic.

VIRKON S can be applied as an aerial spray — without discomfort to people or animals present — can be used in manual cleaning operations or applied using pressure cleaning equipment.

VIRKON S has been widely tested by the Central Veterinary Laboratory, Weybridge and the Animal Virus Research Institute, Pirbright — as a virucide — and activity confirmed against all virus families screened — affecting all species — avian, large animals, humans. It inactivates the most resistant viruses.

VIRKON S has been tested by Chester Beatty Cancer Research and proved effective against the Aids virus.

Extensive tests with various species of livestock have been carried out at Cambridge University by Dr D W B Sainsbury proving the safety and efficacy of the product.

Biological and Chemical Reactions

The wide spectrum biocidal activity of VIRKON S is contributed by Potassium Monopersulphate a powerful oxidising agent.

The exact nature of its biological activity is not known.

It may promote oxidisation of cellular material by acting on the lipo protein cytoplasmic membrane and disrupting the osmatic barrier. The exact role of the simplet oxygen is not known...

The nature of the chemical reaction of VIRKON S cannot be precisely stated.

The reaction is complex and the probable chain reaction of VIRKON S is as follows:

DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

PRODUCT NAME: VirKon S	12.	EPA REG.NO/FILE SYMBOL 778-62 OR	3. FORMULATOR'S EXEMPTION SELECTED	4. PAGE 1 OF 3
5. APPLICANT'S NAME AND ADDRESS	6	APPLICATION FOR	YES NO X	
A. H. Robins Company, Inc. 1405 Cummings Drive		REGISTRATION DATED 3 / 25/89	7. NAME OF ACTIVE INGREDIENT(S):	
P. O. Box 26609 Richmond, VA 23261-6609	•	Mo. Day Yr.	Potassium Monopersulfate; Sodi	um Chloride

8. DATA REQUIREMENTS		9. SOURCE OF DATA SATISFYING REQUIREMENT							10. MRID NUMBER,				
8a. Regulation Part 158/ Guideline Number	Name of Test	9a. Submitted by Applicant	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter Enclosed	9e.	9f. N.A. or Waiver or other (Explain)	EPA NUME	ACCES BER OF IDEN	SSION OR OTHER TIFYING			
§158.20	PRODUCT CHEMISTRY	1											
61-1	Identity of ingredients	3/25/89		·									
61-2	Statement of composition	3/25/89											
61-3	Discussion of formation of ingredients	3/25/89											
62-1	Preliminary analysis						N.A.						
62-2	Certification of limits	3/25/89			-6-			1.					
62-3	Analytical methods for enforcement limits	3/25/89											
63-2	Color	3/25/89						1					
63-3	Physical state	3/25/89											
63-4	Odor	3/25/89											
63-5	Melting point						N.A.						
63-6	Boiling point						N.A.						
63-7	Density, bulk-density, or specific gravity	3/25/89								311			

DATA REQUIREMENT LIST FOR THE OWNER SUPMISSION METHODE SUPPORT

			STATE	AND THE RESERVE OF THE PARTY OF
1.	2.	EPA REG.NO/FILE SYMBOL	3.	4.
PRODUCT NAME: VirKon S	1	778-950R	FORMULATOR'S FXFMPTION SELECTED	PAGE 2 SE 3
5.			YES NO X	
APPLICANT'S NAME AND ADDRESS	6.	APPLICATION FOR		
A. H. Robins Company, Inc.		REGISTRATION DATED	7. NAME OF ACTIVE INGREDIENT(S):	
1405 Cummings Drive		3 / 25/ 89	Potassium Monopersulfate; Sodium	Chlorido
P. O. Box 26609		Mo. Day Yr.	i rocciositan nonopersurrate, sourcin	Cirtor rde
Richmond, VA 23261-6609	1			
THE R. P. LEWIS CO., LANSING MICH. 49-140-140-140-140-140-140-140-140-140-140				
		1		110.

	REQUIREMENTS	9.		F DATA SATISE		EMENT			D NU		
8a. Regulation Part 158/ Guideline Number	Name of Test	9a. Submitted by Applicant		9c. Submitted by another person/firm (name)	9d. Pennission Letter Enclosed	9e. Public Litera- ture	9f. N.A. or Waiver or other (Explain)	NUM	IDE	OR C	THER
\$158.20	PRODUCT CHEMISTRY (Continued										
63-8	Solubility						N.A.				
63-9	Vapor pressure						N.A.				
63-10	Dissociation constant						N.A.				
63-11	Octanol/water partition coefficient						N.A.				
63-12	рH	3/15/89)								
63-13	Stability						N.A.				
63-14	Oxidizing/reducing reaction	3/25/89									
63-15	Flammability	3,23,0,					N.A.				
63-16	Explodability	3/25/89									
63-17	Storage stability	3/25/89									
63-18	Viscosity						N.A.				
63-19	Miscibility						N.A.				

DATA REQUIREMENT LING FOR THE CER SUBMISSION ME D OF SUPPORT

PRODUCT NAM	ME: VirKon S		O/FILE SYMI 8 -02 or	FORMULA'	TOR'S EXEMPT		CTED 4.	AGE	3	of	3	_
APPLICANT'S A. H. Robi 1405 Curmi P. O. Box	PPLICANT'S NAME AND ADDRESS A. H. Robins Company, Inc. A. Governings Drive 3 / 25 / 89 6. APPLICATION FOR REGISTRATION DATED 3 / 25 / 89					NGREDIEN		lor	ide			
	REQUIREMENTS	9.		F DATA SATIS				- 3	ID N		BER,	
8a. Regulation Part 158/ Guideline Number	Name of Test	9a. Submitted by Applicant	Submitted	9c. Submitted by another person/firm (name)		1	9f. N.A. or Waiver or other (Explain)	NUI EPI NUI	ABER	R OR	SSION ROIN PIFY	HER
§158.20	PRODUCT CHEMISTRY (continued											
63-20	Corrosion characteristics	3/25/89										
63-21	Dielectric breakdown voltage						N.A.	-	-	-	+	-
§158.135	TOXICOLOGY											
81-1	Acute oral LD-50, rat	3/25/89										
81-2	Acute dermal LD-50	3/25/89										
81-3	Acute inhalation LC-50, rat	3/25/89										
81-4	Primary eye irritation, rabbit	3/25/89										
81-5	Primary dearmal irritation	3/25/89										
81-6	Dermal sensitization	3/25/89										,

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United States Environmental Protection Agency Washington, DC 20460

Certification with Respect to Citation of Data

Form Approved OMB No. 2070-0060 Approval expires 9-30-90

A. H. Robins Company, Inc.

1405 Cummings Drive
P. O. Box 26609
Richmond, VA 23251-5609

Product Name
Virkon S

Date of Application

3/25/89

- 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.
- 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I am the original data submitter, or have obtained the written permission of the original data submitter to cite that study.
- 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

- All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)
- Those companies who have submitted the studies which I have cited (Selective method).

/		
Signature	Name and Title Mgr., Regulatory Date	
Malay	Affairs, Pet Care Products R&D 3/25/89	

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Signature /	Name and Tit	e Mgr., Reg	gulatory	Date
1.1 %	Affairs,	Pet care I	roducts Ra	.
Ahlaure 11	on H. Wayne	Moran		3/25/39

EPA Form 8570-29 (7-86)

United States Environmental Protection Agency Washington, DC 20460

⊕EPA

Certification with Respect to Citation of Data

Form Approved OMB No. 2070-0060 Approval expires 9-30-90

Applicant's Name and Address

A. H. Robins Company, Inc. 1405 Cummings Drive P. O. Box 26609 Richmond, VA 23261-6609 EPA File Symbol/Registration Number

Product Name

VirKon S

Date of Application

3位5/静。

- 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product or of any other product that is identical or substantially similar, and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application.
- 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study, I am the original data submitter, or have obtained the written permission of the original data submitter to cite that study.
- 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study:

I am the original data submitter; or I have obtained the written permission of the original data submitter to cite that study; or

I have notified in writing the companies who have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act; and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: (Check one)

- All companies listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method). (Also sign the General Offer to Pay Statement below.)
- Those companies who have submitted the studies which I have cited (Selective method).

Name and Title Mgr., Regulatory Date
Affairs, Pet Care Products Rail 3/25/89

Name and Title Mgr., Regulatory Date
Affairs, Pet Care Products Rail 3/25/89

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required by FIFRA sec. 3(c)(1)(D) and 3(c)(2)(D).

Name and Title Mgr., Regulatory
Affairs, Pet care Products RAD
H. Wayne Moran
3/25/89

EPA Form 8570-29 (7-86)

315

H. Wayne Moran

EPA Form 8570-1 (Rev. 4-88) Previous editions are obsolete.

2. Signature

4. Typed Name

3. Title Mgr., Regulatory Affairs, Pet Care Pro-

ducts R&D

5. Date Signed

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

- Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
- 2. Confidential Statement of Formula (EPA Form 8570-4).
- 3. Five copies of draft labeling.
- 4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8 1/2 x 11 inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an $8 1/2 \times 11$ inch file. Mockup labels significantly smaller than $8 1/2 \times 11$ inches should be mounted on $8 1/2 \times 11$ inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in three copies. In order to facilitate review, each type of data submitted must be bound separately, and clearly identified on the front cover including the date submitted.

A copy of the application form and a copy of the label should be bound in each separate volume of the data.

All Data For Which Claims of Confidentiality Are Asserted Must Be Submitted, Bound Separately and Clearly Marked As Such

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Section 1, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Sections 1, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

- 1. Company/Product Number Insert your company number,
 Company/Product Number Insert your company number,
 Company/Product Number Insert your company number,
 - signed to yours a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
- 2. Date Fill in the appropriate date.
- 3. Product Manager If known, fill in the name and number of the Product Manager.
- 4... * . Proposed Classification Specify the proposed classification but this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters.

An applicant Not residing in the United States must have an authorized agent residing in the United States to act for

- them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

 Subject of Amendment Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Specify the net contents of all retail containers for your product.
- Sire(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- Manner in which label is affixed to product Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
- 6. EPA Usc Only.

